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Supplemental Risk Assessment Guidance for the Superfund Program

PART 1 - Guidance For Public Health Risk Assessments

PART 2 - Guidance For Ecological Risk Assessments

DRAFT FINAL

June 1989

Prepared by the U.S. EPA Region I
Risk Assessment Work Group

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The guidance manual was developed to address the practical aspects and issues pertaining to the Superfund risk assessment process for both the public health and environmental concerns. Part 1, Guidance for Public Health Risk Assessments, supplements the Superfund Public Health Evaluation Manual (SPHEM) and Superfund Exposure Assessment Manual (SEAM) and the Endangerment Assessment Handbook. Explicit guidance on technical matters which should be followed in developing public health risk assessments for EPA Region I. The guidance addresses hazard identification, dose-response assessment, exposure assessment, risk characterization and uncertainty/limitations. Part 2 of the manual, Guidance for Ecological Risk Assessments, addresses the collection of site-specific data needed to support an ecological risk assessment, describes a framework for conducting the assessments, and provides several specific approaches for assessing risks to systems exposed to chemical contamination in different media.

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DISCLAIMER

The Region I Supplemental Risk Assessment Guidance for the Superfund Program does not represent official U.S. EPA policy. Any attempt to use it as such is beyond the intent of the Region I Office. It is the intent of the Region I Superfund Program to apply the principles contained herein to risk assessments generated for the Region I Superfund Program. In certain circumstances, the Region I Office may take action that deviates from the guidance identified in this manual. Because the EPA Region I Supplemental Risk Assessment Guidance for the Superfund Program was developed as a dynamic document, your comments and constructive criticism will serve to improve the value and utility of the manual and the Region's ability to produce high quality risk assessments.

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Sarah Levinson
EPA Project Manager
May, 1989

U.S. ENVIRONMENTAL PROTECTION AGENCY

REGION 1

DRAFT FINAL
SUPPLEMENTAL RISK ASSESSMENT GUIDANCE FOR THE SUPERFUND PROGRAM

PART 1 - GUIDANCE FOR PUBLIC HEALTH RISK ASSESSMENTS

PART 2 - GUIDANCE FOR ECOLOGICAL RISK ASSESSMENTS

JUNE 1989

PREPARED BY THE U.S.EPA REGION 1
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U.S. ENVIRONMENTAL PROTECTION AGENCY

REGION 1

SUPPLEMENTAL RISK ASSESSMENT GUIDANCE FOR THE SUPERFUND PROGRAM

The U.S. Environmental Protection Agency (EPA) is responsible for implementing the Comprehensive Environmental Response and Compliance Liability Act, and the Superfund Amendments and Reauthorization Act (CERCLA/SARA), collectively known as "Superfund". Superfund requires that the potential threats to public health and the environment be assessed for sites that have been placed on the National Priorities List (NPL). The threats to public health and the environment are evaluated in the risk (or endangerment) assessment, which is conducted as part of the Remedial Investigation or Feasibility Study.

Presently, EPA has several guidance documents that describe the methods and approaches suggested for risk assessments, including the Superfund Public Health Evaluation Manual (SPHEM), the Endangerment Assessment Handbook, and the Exposure Assessment Manual. These and other guidance documents provide the general framework for the Superfund risk assessment. However, experience has shown that risk assessments performed for Superfund sites have had wide variability with respect to structure, content and quality, and that further guidance is needed. In addition, EPA Region 1 recognized a distinct need for Superfund Project Managers to acquire a working knowledge of the basic steps associated with the risk assessment process.

In an effort to establish guidance and continuity in risk assessments within EPA Region 1, a Risk Assessment Work Group was established in early 1987. The Work Group combined the talents and experience of Region 1 environmental scientists, toxicologists, and engineers, NOAA, U.S. Fish & Wildlife, and the REM II and III risk assessment contractors (Clement Assoc. and E. C. Jordan). Within the larger Risk Assessment Work Group, two smaller work groups were established with one devoted to public health issues and the other devoted to environmental issues. With an overall goal of improving quality and consistency in risk assessments, each work group developed a guidance document. These guidance documents were developed to address the practical aspects and issues pertaining to the Superfund risk assessment process for both the public health and environmental concerns.

The result of each work groups' efforts have been summarized in this guidance manual, the Region 1 Supplemental Risk Assessment Guidance for the Superfund Program, which consists of both the public health (Part 1) and the ecological aspects (Part 2) of a risk assessment. As such, it represents the perspective of the Region I Risk Assessment Work Group. Additionally, the Region 1 guidance manual is intended to provide EPA project managers and Superfund contractors with technical information and guidance necessary for conducting and reviewing public health and ecological risk assessments.

Part 1 of this manual, Guidance For Public Health Risk Assessments, serves as a supplement to the Superfund Public Health Evaluation Manual (SPHEM), the Endangerment Assessment Handbook, the Exposure Assessment Manual, and other formal EPA guidance. It was the intention of the work group that developed this guidance to make the supplement as practical and useful as possible. Consequently, the guidance is very explicit on technical matters crucial to the evaluation of human health risk. Public health risk assessments developed for Region 1 should adhere to the guidance in Part 1, and any deviations from the guidance should first be reviewed and approved by the EPA Region 1 risk assessment specialists.

Part 2 of this manual, Guidance For Ecological Risk Assessments, is the first such manual that focuses on considerations for conducting an ecological risk assessment. A similar effort at EPA Headquarters is underway and a Superfund Environmental Evaluation Manual should be available in the near future. Many of the concepts presented in Part 2 are expanded in the Superfund Environmental Evaluation Manual (Interim Final Draft) and Ecological Assessments of Hazardous Waste Sites: A Field and Laboratory Reference Document (USEPA, 1989). The Guidance for Ecological Risk Assessments reviews elements of an ecological risk assessment, as well as the types of data needed in order to evaluate risk to environmental receptors. Because the evaluation of risk to the environment and to whole ecosystems is an extremely broad, new field and is much more site-specific than the public health risk assessment, the Regional Office strongly encourages those undertaking an ecological risk assessment to seek out the advice and the assistance of the Regional Office prior to undertaking such a task.

PART 1

GUIDANCE FOR PUBLIC
HEALTH RISK ASSESSMENTS

DRAFT FINAL

JUNE 1989

U.S. ENVIRONMENTAL PROTECTION AGENCY
REGION 1

PART I

GUIDANCE FOR PUBLIC HEALTH RISK ASSESSMENTS

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PART 1

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GUIDANCE FOR PUBLIC HEALTH RISK ASSESSMENTS

1.0 INTRODUCTION

Part 1 of this manual, Guidance For Public Health Risk Assessments, serves as a supplement to the Superfund Public Health Evaluation Manual (SPHEM), the Endangerment Assessment Handbook, the Exposure Assessment Manual, and other formal EPA guidance. It was the intention of the work group that developed this guidance to make the supplement as practical as possible. Consequently, the guidance is very explicit on technical matters crucial to the evaluation of human health. Public health risk assessments developed for Region 1 should adhere to the guidance contained in Part 1, and any deviations from the guidance should first be reviewed and approved by the EPA Region 1 risk assessment specialists.

Because the public health risk assessment work group assumed the audience had some familiarity with the public health risk assessment process, many of the basic principles behind the "science" of human health risk assessments have not been detailed in this handbook. For this type of introductory information, the reader is referred to the SPHEM and the local library. The EPA Region I Guidance for Public Health Risk Assessments follows the basic format for EPA public health risk assessments. It consists of the following sections: Hazard Identification; Dose-Response Assessment; Exposure Assessment; Risk Characterization; and Uncertainty and Limitations of the Risk Assessment. It is organized as such to provide a useful reference manual.

2.0 HAZARD IDENTIFICATION

Hazard identification is the process of identifying which detected contaminants, or those predicted by modeling, have inherent toxic effects that are likely to be of concern from a public health perspective. This is accomplished, in part, by providing a review of the monitoring and modeling information that has been collected for a particular site.

This section of the guidance document addresses how to characterize and summarize the nature and extent of contamination by the generation of mean statistics, treatment of non-detects and trace value data, and establishment of background contamination. Additionally, two methods are presented for selecting a subset of contaminants (contaminants of concern) that are likely to pose the greatest public health concern. Finally, the need for chemical specific toxicity information and suitable references for this information are identified.

2.1. EXTENT OF CONTAMINATION (TREATMENT OF THE DATA)

In selecting the data to include in the risk assessment, the objective of the risk assessor is to characterize as accurately as possible the extent of contamination. As a result, the boundaries between "contaminated" and "non-contaminated" areas within each medium is of the utmost importance. Careful consideration must be given to the data such that a three-dimensional representation of the extent of contamination can be generated and carried forward through the risk assessment. Because decisions regarding which data to include in the risk assessment are often subjective and have profound influences on the resulting risk estimates, it is strongly encouraged that contractors consult with the Region 1 Risk Specialist on this matter prior to continuing with the risk assessment.

Data summary tables should be developed for each medium sampled (e.g. air, surface water, groundwater, soil). Summary statistics are crucial to the selection of contaminants of concern for the risk assessment. Each data summary table should indicate the frequency of detection (number of detects per number of samples), observed range of concentration, and the mean and maximum value for each contaminant detected in each media. Most importantly, the format and the method used to summarize the information should be clear and consistent across all environmental media.

2.1.1 CALCULATING STATISTICAL MEANS

Either the arithmetic or geometric mean may be used as a statistical method to summarize data. Usually, an arithmetic mean is used for normally distributed data, while a geometric mean is preferred for log-normally distributed data to minimize the influence of outlying data points. Regardless of the statistical method selected, the mean calculation should be consistent across all environmental media. Additionally, the rationale behind the selection of a particular summary statistical method (either the arithmetic or geometric mean) should be discussed in the Hazard Identification.

In determining which samples to use in calculating a mean value, the spatial and temporal distribution of compounds should be considered to avoid biasing the mean. The risk assessor should also be aware of any inherent bias in the sampling design that may tend to influence the mean statistic. It may be appropriate to develop separate mean statistics for "hot spot" areas within a site, particularly when evaluating soil contamination. Air data should also be interpreted with caution due to the wide spatial and temporal distribution that often characterizes air sampling data. Duplicate samples should be averaged and this value used in the mean calculation.

2.1.2 NON-DETECTS AND TRACE VALUE DATA

The results of laboratory analysis of environmental samples are often reported as non-detect (ND). Such results do not necessarily indicate no contamination in the sampled media. When laboratory data are listed as "ND", the risk assessor has several options regarding data treatment: (1) ignore the data points, (2) enter zero as the value, (3) enter 1/2 the limit of detection for the sample and contaminant, or (4) enter the limit of detection for the sample and contaminant. Because of the significant differences between sites, a single recommendation for treatment of "ND" data cannot be made. The following discussion presents several considerations for using "ND" data. The risk assessor should clearly state the approach and rationale used in interpreting the "ND" data in the Risk Assessment.

The risk assessor should determine whether the sampling program was biased or unbiased. Often environmental samples are screened with on-site instruments prior to laboratory analysis. Only samples showing the presence of contamination are actually submitted for analysis. In this case, the laboratory data reflect a biased sampling of the site. The use of "ND" samples from such a sampling program may be expected to have a higher probability of actually being contaminated than would samples from an unbiased sampling program.

The spatial distribution of detects and non-detects should be determined. If they are clearly segregated, it may be appropriate to ignore "ND" samples and compute summary statistics for the well-defined contaminated area, rather than for the site as a whole. The distribution of all contaminants should be considered in this analysis.

The statistical distribution of the sample values should be determined. If the values are log-normally distributed and the geometric mean has been chosen as the appropriate summary statistic, then zero cannot be used for "ND" samples. Either a value of 1/2 the limit of detection must be used for "ND" samples or they should simply be ignored.

The effects of sample dilution in the laboratory also must be considered. Laboratories must often dilute samples prior to analysis because of analytical limitations of the equipment. If the sample limit of detection is very high due to dilution effects, the risk assessor should determine whether there are other samples in which the contaminant was detected. If the limit of detection is high and the contaminant was not detected at quantified levels in any sample, it may be inappropriate to presume that the contaminant is present at 1/2 the limit of detection. If, on the other hand, a contaminant is detected in numerous samples at quantified levels, it may be inappropriate to treat a "ND" sample as zero.

Trace values in data also require careful consideration by the risk assessor. Often the instrument limit of detection is lower than the contractual limit of detection. If a contaminant is detected at a quantified level that is below the contractual limit of detection, the laboratory is required to flag the value as a "trace" value. Often this value is reported, however it will be presented as the detection limit with merely a footnote indicating that it did not exceed the detection limit. It is recommended that samples having trace values be included in generating summary statistics for a site. If the actual value is available, it is appropriate to include it. Otherwise, it may be appropriate to substitute 1/2 the contractual limit of detection for the value. The risk assessor should clearly explain the data treatment methods chosen and the rationale for choosing such methods.

2.1.3 BACKGROUND AND/OR NATURALLY OCCURRING CONTAMINATION

Background and/or natural levels of contaminants should be characterized for each media, especially for metals that may be naturally occurring in soils or ground water. Background levels of contamination are useful as they serve to distinguish between site and non-site related sources of contamination and can help identify naturally occurring levels of metals in soils and groundwater. Preferably upgradient samples collected in the field should be used to characterize background levels of contamination. In the absence of field determined background data, representative values of naturally occurring (metal) contamination may sometimes be obtained from the literature. These literature values however, are to be used as a last resort.

In selecting contaminants of concern for the risk assessment (Section 2.2), careful consideration should be given to naturally occurring levels of metal contamination in soils and groundwater. Other pollutants (man-made) that were detected in background samples upgradient of the site can be included as contaminants of concern though they may warrant some discussion in the final assessment of risk.

2.2. SELECTION OF CONTAMINANTS OF CONCERN

The number of contaminants detected at many Superfund sites is often too large to fully quantify all possible health risks. Thus a subset of these compounds, known as contaminants of concern, may be selected to serve as the focus for further risk characterization efforts. If a subset of all chemicals detected will be carried through the analysis, it is important to select those chemicals that are likely to contribute most to the overall risk. Selection of contaminants of concern should be based on concentration, toxicity, frequency of detection, sample location, and the chemical and physical properties of the compound which determine its environmental fate and transport. On occasion, toxicity information may not be available for a prevalent chemical detected at high levels. In this case, the use of structure activity information (applying toxicity information from another chemical of similar structure) may be an option. If structure activity information is used, attention should not only be paid to identifying compounds of similar chemical structure but also to selecting compounds exhibiting the same type of effect (carcinogenic/noncarcinogenic) and affecting similar target organs. A chemist should be consulted when structure activity relationships are utilized.

Contaminants of concern should be selected for each environmental media. Aquatic and/or terrestrial contaminants of concern should be determined separately from those used for public health risk assessments. Naturally occurring contamination (e.g. inorganics in soil) and contaminants detected in sample blanks, should be carefully considered when selecting contaminants of concern.

Evaluations and data use decisions for contaminants of concern can be greatly facilitated by generating a frequency distribution (histogram) for the predominant contaminants of concern in each media. The resultant visual display of the range and distribution of concentrations aids in data evaluation, and serves to help visualize the appropriate statistical method (arithmetic vs. geometric mean) that should be used in the reporting of the data.

Selection of contaminants of concern can be accomplished through either a qualitative process (Section 2.2.1), or through a quantitative selection process (Section 2.2.2). Regardless of the selection method chosen, all of the factors described above should be considered when selecting contaminants of concern. In addition, the Risk Assessment should provide appropriate justification for the inclusion or exclusion of hazardous chemicals as contaminants of concern.

2.2.1 QUALITATIVE SELECTION OF CONTAMINANTS OF CONCERN

The qualitative approach relies heavily on the expertise of the risk assessor in selecting the final list of contaminants of concern. Because of this, it is extremely important for the risk assessor to be quite knowledgeable on each of the parameters identified above (toxicity, mobility, persistence, frequency of detection, etc) for each contaminant. One method that can assist with the qualitative selection process is to group the contaminants into chemical classes. The site data should be comprehensively reviewed to ensure that each chemical class of contamination at the site has been adequately represented. Once organized into groups, each group or class is then collectively evaluated on the basis of the toxicity, persistence frequency of detection, etc.

2.2.2 QUANTITATIVE SELECTION OF CONTAMINANTS OF CONCERN (SPHEM Method)

If the quantitative approach (SPHEM method) is used to select contaminants of concern, all chemicals detected should be considered in the selection process, regardless of the availability of a toxicity constant. When a toxicity constant is lacking for a particular chemical, the necessary toxicity or other information should be obtained from the current literature and evaluated qualitatively as described above in Section 2.2.1. It is important to determine whether the information listed in the SPHEM reflects the most current information available. The Toxics Integration Branch (202-475-9486) at EPA headquarters provides periodic updates of the SPHEM and its appendices, and should be consulted for information if the SPHEM method is to be used. A description of this method appears in the SPHEM and thus will not be described further.

2.3. TOXICITY PROFILES

Information on the toxicity of the contaminants of concern should be tailored to two different audiences: 1) the general reader with little or no familiarity with the science and technical terms used, and 2) the more informed, technical reader. For ease in understanding, toxicity information for the lay person should be included in the Hazard Identification while the more technical summary information should be presented in an appendix. In addition, the most current toxicity information should be used for the toxicity profiles. Because there often is an overlap between the ecological risk evaluations, toxicity profiles can be developed such that they include information pertinent to both types of assessment.

2.3.1 GENERAL TOXICITY SUMMARY

The Hazard Identification should include, a two to three paragraph summary of the toxicity of each contaminant of concern. The general summary should not be highly technical in nature, and it should be understandable to the lay reader. The toxicity summary should outline the acute and chronic effects (carcinogenic and noncarcinogenic) associated with exposure to each contaminant of concern, and it should include the concentrations at which adverse effects are expected in humans. Health based Applicable or Relevant and Appropriate Requirements (ARARs), and other guidelines and dose-response information should be summarized in a table(s), along with a section in the text explaining the source of these values.

2.3.2 TECHNICAL TOXICITY SUMMARY

A technical toxicity profile for each contaminant of concern should be included in an appendix to the Risk Assessment. The technical toxicity profile should be more in-depth than the summary provided in the main body of the report. Each profile should summarize acute and chronic effects related to each compound, including systemic, carcinogenic, mutagenic, reproductive, and teratogenic effects. The profile should cite references and the animal or human study which was used as the basis for the human health criteria. Toxicity profiles should include the EPA classification for carcinogens.

2.3.3 SOURCES OF TOXICITY PROFILE INFORMATION

The following documents and/or databases provide useful information for toxicity profile development:

1. Integrated Risk Information System (IRIS) -
   Database which provides updated information of EPA standards and criteria for many chemical, contact Mike McLaughlin of DIALCOM, Inc at (202) 488-0550 for access information.

2. Health Effects Assessments - Summary of toxicity information for 58 chemicals found at Superfund Sites.
3. Health Assessment Documents
4. Ambient Water Quality Criteria (AWQC) Documents
5. Health Advisory Background Information
6. Agency for Toxic Substance and Disease Registry (ATSDR) Toxicity Profiles
7. International Agency for Research on Cancer (IARC)
8. Superfund Public Health Risk Evaluation Database (PHRED)

3.0 DOSE-RESPONSE ASSESSMENT

The dose-response portion of the Risk Assessment provides the scientific information that relates chemical exposure (dose) to expected health effects (response.)

This section of the guidance document identifies and discusses information on the dose-response relationships necessary for the evaluation of carcinogenic and noncarcinogenic effects of the contaminants of concern. Because the standards and guidelines developed by EPA are evolving, it is extremely important for risk assessors to consult the most recent guidance. EPA policy now dictates the use of the IRIS on-line database for dose-response information. This is because IRIS is routinely updated. In addition, other on-line databases (PHRED) can serve as useful resources for information though caution must be used because they often tend to be somewhat outdated.

Dose-response information can appropriately be conveyed in table form with one table for carcinogenic effects and a second table for noncarcinogenic effects. For carcinogenic effects, the compound, cancer weight of evidence, cancer potency factor $(mg/kg/day)^{-1}$, and a reference for the cancer potency factor (including date) should be included in the table. The table for noncarcinogenic effects should include the compound name, a brief description of the critical effect/basis for the reference dose (RfD) (i.e. CNS depression, liver toxicity), the RfD or other relevant measure of noncarcinogenic potency $(mg/kg/day)^{-1}$, and a reference for the RfD (including date of access to IRIS). Additionally risk assessors should take care such that noncarcinogenic effects of known or suspect carcinogens are not overlooked in the dose-response assessment. The sections that follow are to assist individuals in the identification of appropriate dose-respose information for both carcinogenic and noncarcinogenic health effects.

3.1. CARCINOGENIC EFFECTS

The most current EPA cancer potency estimates should be used to evaluate the carcinogenic effects of known or suspect carcinogens. The potency estimates should be reported consistently in units of (mg/kg/day)-1. If route-specific, cancer potency estimates are available, they should be identified and used accordingly. If a cancer potency estimate is not available, it may be appropriate to use the potency factor for a structurally similar compound if structure activity information is available. A brief discussion of the EPA classification scheme for carcinogens as well as the cancer weight of evidence for each carcinogen should be included in the evaluation.

3.1.1 WEIGHT OF EVIDENCE FOR CARCINOGENICITY

There are varying degrees of confidence (referred to as weight of evidence for carcinogenicity) relating exposure to a given chemical and the likelihood that the chemical causes cancer in humans. EPA has a system for characterizing the overall weight of evidence for a chemical's carcinogenicity based on: (1) the quality of evidence from human studies, (2) the quality of evidence from animal studies, and (3) other supportive information such as mutagenic effects or structure-activity data. EPA's final classification of the overall weight of evidence is organized as follows:

Group A--Human Carcinogen

This category indicates that there is sufficient evidence from epidemiological studies to support a causal association between an agent and cancer in humans.

Group B--Probable Human Carcinogen

This category generally indicates that there is at least limited evidence from epidemiological studies of carcinogenicity to humans (Group B1) or that, in the absence of positive data on humans, there is sufficient evidence of carcinogenicity in animals (Group B2).

Group C--Possible Human Carcinogen

This category indicates that there is limited evidence of carcinogenicity in animals in the absence of positive human data.

Group D--Not Classified

This category indicates that there was no data to evaluate or that the evidence for carcinogenicity in humans and in animals was inadequate, at best.

Group E--No Evidence of Carcinogenicity to Humans

This category indicates that there is no evidence for carcinogenicity in at least two adequate animal tests in different species or in both epidemiological and animal studies.

3.1.2 GROUPS OF CARCINOGENIC CHEMICALS

Convenience and/or convention has led to grouping similar compounds together and collectively referring to them by a single name. These groups or mixtures of carcinogenic chemicals are often present at Superfund sites. Examples of these chemical groups include:

- Polychlorinated dibenzo-p-dioxins (PCDDs) and Polychlorinated dibenzofurans (PCDFs)
- Polycyclic aromatic hydrocarbons (PAHs)
- Polychlorinated biphenyls (PCBs)

These groups usually consist of many related chemical compounds with differing chemical, physical, and toxicological properties. Evaluating risks associated with these type of chemical mixtures is sometimes more complex than the traditional single compound evaluation. Additionally, evaluation of the risk from these types of mixtures is often more uncertain as many mixtures have not been well characterized toxicologically. Several examples of approaches used to evaluate these groups of compounds are described in the following sections.

3.1.2.1 PCDDs and PCDFs

The family of PCDDs consist of 75 related compounds, each containing between one and eight chlorine atoms. PCDFs consist of 135 compounds. Each member of the PCDD and PCDF family that has a unique chemical structure is called a congener. There is considerable variation among the congeners with regard to their distribution in the environment, their chemical and physical properties, and their toxic effects. Among this large family of compounds, most toxicological studies have been conducted with only two compounds, 2,3,7,8-TCDD and 2,3,7,8-TCDF.

The EPA has developed a cancer potency factor for 2, 3, 7, 8 TCDD that can be used to evaluate the potential risks associated with other PCDDs and PCDFs. In this approach, the PCDDs and PCDFs are divided into subclasses, and each subclass is characterized by a potency estimate relative to that of 2,3,7,8-TCDD; this relative potency is defined as a toxic equivalency factor (TEF). The concentration of each component in the mixture is then multiplied by its respective TEF to derive a concentration in "2,3,7,8-TCDD equivalents". By combining this information with the toxicity information on 2,3,7,8-TCDD, the risk associated with the mixture of PCDDs/PCDFs can be estimated.

3.1.2.2 PAHs

The approach that can be used to evaluate risk associated with exposures to PAHs differs somewhat from that used for PCDDs/PCDFs. Not all PAHs have been demonstrated to be carcinogenic, and some carcinogenic PAHs are clearly more potent than others. For practical purposes, many PAHs may be separated into one of two categories--either "carcinogenic" or "noncarcinogenic".

An approach currently suggested by EPA Region I involves the application of the cancer potency factor for benzo[a]pyrene (B[a]P) to only those PAHs for which we have suggestive evidence that the PAH may cause cancer. The term that will often be used to refer to this subclass is carcinogenic PAHs or cPAHs. In using this approach, one also assumes that all carcinogenic PAHs have the same potency as B[a]P and that their effects are additive.

Use of the carcinogenic potency factor of B[a]P for carcinogenic PAHs may result in overestimation of risk because B[a]P is considered to be one of the most potent of the carcinogenic PAHs, and B[a]P is likely to constitute only a fraction of the mixture of carcinogenic PAHs present at a site. On the other hand, many other PAHs that are not routinely analyzed for at Superfund sites may have carcinogenic potential. Thus, this approach may not account for some carcinogenic PAH constituents because they haven't been identified or classified by EPA as having carcinogenic potential.

The group of PAHs which lack suggestive evidence of carcinogenicity (i.e. there is no evidence or inadequate evidence of carcinogenicity), should be evaluated as described in Section 3.2 for noncarcinogenic effects using the reference dose for naphthalene as a surrogate for the mixture.

3.1.2.3 PCBs

PCBs represent another chemical mixture that is often detected at Superfund sites. PCBs are mixtures of chlorobiphenyls. The mixtures that were manufactured in the U.S. were given the trade name "Arochlor" and are usually distinguished by a four digit number. Arochlor 1260, for example, is on average, comprised of 60% chlorine by weight (i.e., based on the last two digits). EPA has developed a cancer potency factor for Arochlor 1260 and this potency factor is usually applied to the total mixture of PCBs detected at a site to evaluate risk regardless of the particular Arochlor detected.

In estimating the potential risks associated with exposures to chemical mixtures such as the PCDDs, PCDFs, PAHs, PCBs, and others, the risk assessor should keep in mind the major assumptions and uncertainties affecting his or her analysis, especially the fact that many members of a class of carcinogens are evaluated using a potency factor derived from only one member of the class.

3.2 NONCARCINOGENIC EFFECTS

Noncarcinogenic compounds are thought to have threshold dosage levels below which adverse effects are not expected. Examples of noncarcinogenic effects which have served as the basis for dose-response estimates include enzymatic changes and changes in body weight. In order to help assimilate and weigh the importance of the many noncarcinogenic standards and guidelines, Sections 3.2.1 and 3.2.2 contain a hierarchy of available criteria for evaluating both chronic and acute noncarcinogenic effects.

3.2.1. CHRONIC EFFECTS

The following hierarchy of standards and guidelines is to be used as a general frame of reference for the dose-response section. There may be instances in which deviations may be warranted depending on the quality of the particular estimate. The dose-response values selected for the risk assessment should represent the most current toxicological information.

3.2.1.1. REFERENCE DOSE

The reference dose (RfD) represents EPA's preferred criterion for evaluating noncarcinogenic effects. The RfD corresponds to EPA's identification of the threshold effects level with an added margin of safety. The IRIS database maintains a current listing of all the verified RfDs which are reported in units of mg/kg/day. By definition, the RfD is an estimate of an average daily exposure level below which significant, adverse noncarcinogenic health effects are not expected. Reference doses were originally developed based on a lifetime exposure level, however, subchronic Rfds are now available for certain compounds. RfDs can be established for carcinogenic compounds having noncarcinogenic (systemic, teratogenic, reproductive) health effects as well. Thus, careful attention should be given to ensure that possible noncarcinogenic effects of carcinogens are also included in the assessment. Most RfDs have been developed for the oral route of exposure though work is presently underway to develop RfDs for the inhalation route of exposure as well. As more inhalation RfDs become available, the use of route specific RfDs will be preferable. The toxicity endpoint upon which the RfD is derived and the uncertainty factor used in the calculation of the RfD should be presented and discussed in the analysis.

The RfD is derived from the following equation:

$$\text{RfD (mg/kg/day)} = \frac{\text{NOAEL or LOAEL}}{\text{U.F.}}$$

where the NOAEL (No Observable Adverse Effect Level) represents the dose of a chemical at which there is no statistically or biologically significant difference in frequency of an adverse effect between the exposed population and its appropriate control. The LOAEL (Lowest Observable Adverse Effect Level) represents the lowest dose where a statistically significant difference in the frequency of an adverse effect is observed. Both the NOAEL and the LOAEL are reported in terms of mg/kg/day. The uncertainty factor (U.F.) is included to account for interspecies and intraspecies differences, severity of the adverse effect, and the adequacy of the data. Therefore, the magnitude of the uncertainty factor will vary from chemical to chemical. In the absence of RfD values, a reference dose equivalent may be determined using the relationships described in the following sections.

3.2.1.2. Drinking Water Regulations and Guidance Derived Under The Safe Drinking Water Act (SDWA)

a. Drinking Water Equivalent Level (DWEL)

The drinking water equivalent level (DWEL) can be described by the following equation:

$$\text{DWEL (mg/l)} = \frac{\text{RfD} \times 70\ \text{kg}}{2\text{L}}$$

where RfD = reference dose, 70 kg = body weight for an adult, and 2 L = daily water consumption for an adult. DWELs can be adjusted back to an RfD (mg/kg/day) by simply solving the equation for the RfD.

b. Lifetime Health Advisory (HA) and Maximum Contaminant Level Goal (MCLG)

The MCLG (either proposed or final) and the lifetime HA are expressed in units of mg/l or ug/l as developed by the Office of Drinking Water. The MCLG and the lifetime HA are guidelines derived strictly on health considerations. The MCLGs for Class A and B carcinogens (known or probable human carcinogens) are based on carcinogenic effects and thus are not appropriate for use in the assessment of non-carcinogenic effects. By definition, lifetime health advisories are not available for Class A and B carcinogens.

For Class C, D and E compounds, the MCLG and the lifetime health advisory are equivalent. It is appropriate to use these dose-response values in the evaluation of noncarcinogenic risk with the following adjustments to derive an RfD in units of mg/kg/day:

1. Class C compounds (possible human carcinogens)

$$MCLG = Lifetime\ HA = \frac{DWEL \times RSC}{U.F.}$$

Where RSC refers to the Relative Source of Contribution (percent). The RSC is the contribution to total exposure from the ingestion of drinking water. For all compounds, the RSC is 20%, except for the following:

barium	83%
cadmium	25%
chromium	71%
nickel	43%

The term U.F. refers to an uncertainty factor, normally a factor of 10, and is applied to account for possible carcinogenic effects of class C compounds.

2. Class D compounds (not-classifiable) and Class E Compounds (non-carcinogens)

$$MCLG = Lifetime\ HA = DWEL \times RSC$$

Lifetime HAs and MCLGs for Class D and Class E compounds simply need to be adjusted to discount the relative source of contribution from drinking water and adjusted for ingestion rate and body weight in order to derive the equivalent RfD.

3.2.1.3 Acceptable Intake Chronic (AIC) and Ambient Water Quality Criteria (AWQC)

a. Acceptable Intake Chronic (AIC)

AICs are acceptable daily average intakes for lifetime (chronic) exposures below which adverse effects are not expected. These are derived by EPA and are listed in the SPHEM. They are expressed in units of mg/kg/day for both the oral and inhalation routes of exposure and can be used without adjustment as a surrogate for a RfD when all of the above criteria are unavailable.

b. Ambient Water Quality Criteria (AWQC)

> The AWQC developed by EPA for the protection of human health are reported in units of mg/l for toxicity (noncarcinogenic) protection. Often two AWQC values will be available- one corresponding to the ingestion of water and organisms and a second corresponding to the ingestion of organisms alone. Either one of these values (depending on which is more relevant to the exposure of concern) can be adjusted to correspond to units consistent with a reference dose value.

3.2.1.4. Acceptable Daily Intake (ADI), and Suggested No Adverse Response Level (SNARL)

Other values that can be used if the aforementioned criteria are not available, include the ADIs and SNARLS derived by non-regulatory agencies such as the National Academy of Sciences and the World Health Organization. Proper adjustments should to be made to reflect the dose in mg/kg/day and to discount the relative source of contribution from drinking water, if necessary.

In summary, care should be taken to use the most recent and most appropriate dose-response value for the risk assessment. EPA Region I should be contacted for guidance if several different values are available or if there is a question regarding which dose-response value is the most appropriate to use.

3.2.2 ACUTE AND SUBCHRONIC GUIDELINES AND STANDARDS

Unlike chronic values, a structured hierarchy does not exist for acute and subchronic values because the most appropriate dose-response value is very dependant on the duration of exposure. Sections 3.2.2.1 through 3.2.2.4 briefly summarize four dose-response parameters that can be used to evaluate acute and subchronic exposures.

3.2.2.1 One and Ten Day Health Advisories

One and ten day health advisories represent short term exposure limits (ug/l) developed by the Office of Drinking Water to protect against non-carcinogenic health effects. For longer term but less-than-lifetime exposures, examination of longer term health advisories and acceptable intake subchronic (AIS) values is recommended.

3.2.2.2 Subchronic Reference Dose

When available, a subchronic reference dose should be consulted for exposures that range from several months to several years in duration. Like the chronic reference dose, the subchronic reference dose is expressed in units of mg/kg/day and it corresponds to an estimate of the daily exposure level, below which adverse noncarcinogenic health effects are not anticipated when exposure is for a fraction of a lifetime.

3.2.2.3 Longer Term Health Advisories

These represent guidelines to protect against noncarcinogenic effects resulting from longer term but less-than-lifetime exposures (several months to several years). They are reported in terms of ug/l and are derived separately for adults and children.

3.2.2.4 Acceptable Intake Subchronic (AIS)

The acceptable intakes subchronic (AIS) values serve as another guideline for subchronic exposures and are reported in units of mg/kg/day. The use of AIS values is appropriate when exposure ranges from several months to several years.

3.3. APPLICABLE OR RELEVANT AND APPROPRIATE REQUIREMENTS (ARARs)

Because some of the standards and guidelines described above will be designated as applicable or relevant and appropriate requirements (ARARS) in the Feasibility Study portion of the remedial process, a table of the health related ARARS can be included in the risk assessment. Presentation of a table of ARARS is optional in the risk assessment since ARARs are usually presented in other portions of the Feasibility Study.

If health related ARARs are included in the Risk Assessment, both Federal and State Health based ARARs should be included. State developed ARARs can be obtained from either the state or the Region I risk assessment specialist. In identifying such ARARs, the risk assessor should state that the ARARS were not necessarily used to assess the health risks. Comparison to ARARS however can be used to assess the attainment or non-attainment of institutional requirements. Assumptions and stipulations incorporated in the derivation of ARARS should be discussed in the report if ARARs are presented.

For example, Maximum Contaminant Levels (MCLs) established under the Safe Drinking Water Act are ARARs but because the MCLs are not always based strictly on health considerations, they may not be relevant to the dose-response assessment. MCLGs however, are relevant to the dose-response section because they are based solely on health considerations yet they are not usually regarded as ARARs. (In using both MCLs and MCLGs, note that values can be listed as "proposed" MCLs/MCLGs, or "final". Because long delays are common before proposed values become final, it is the opinion of EPA Region I that proposed MCLs/MCLGs can be used in the Risk Assessment provided that a reference is given.)

4.0 EXPOSURE ASSESSMENT

The exposure assessment identifies pathways and routes by which site contaminants may reach receptors and contaminant concentrations at the points of exposure. This information is then integrated with known or predicted activity patterns such that an estimated exposure dose for each pathway and each contaminant of concern is generated.

In this section, general methods and approaches used for conducting an exposure assessment are described. Four basic elements of any exposure assessment are identified below along with the section in which each is addressed.

1. Identification of exposure pathways (Section 4.1)
2. Estimation of exposure point concentrations for each selected pathway (Section 4.2)
3. Estimation of exposure dose for each selected pathway (Section 4.3)
4. Development of exposure scenarios (Section 4.4)

Exposure pathways may involve several media, and the exposure assessment must address the exposure scenarios for each media. Methods and approaches for exposure evaluations specific to each media are presented in Sections 4.5 (Groundwater), 4.6 (Surface Water), 4.7 (Soil) and 4.8 (Air).

4.1 IDENTIFICATION OF EXPOSURE PATHWAYS

As described in the Superfund Public Health Evaluation Manual (USEPA 1986), an exposure pathway consists of four elements:

1. A source and mechanism of chemical release into the environment.
2. An environmental transport medium for the released contaminant (e.g., air) and/or a mechanism of contaminant transfer from one medium to another (e.g., deposition of particles onto soil).
3. A point of potential contact of humans or biota (the receptors) with the contaminated medium (the exposure point).

4. An exposure route (e.g., inhalation) at the exposure point.

When all four of these elements are present, an exposure pathway is considered "complete". For each public health risk assessment, exposure pathways considered complete should be identified by the risk assessor. Some of the more common exposure pathways quantitatively evaluated in risk assessments are briefly identified below by the environmental medium of exposure. Note that there often are many potential pathways of exposure, only some of which are presented below.

> Air: Both indoor and outdoor exposures could result from inhalation of particulate matter and/or gaseous compounds from a nearby site.
>
> Groundwater: Exposures to chemicals migrating through groundwater from a site could result in the ingestion of contaminated water or in the inhalation of volatile organic compounds resulting from volatilization from household water usage.
>
> Surface Water: Exposures to chemicals in surface water could occur as a result of incidental ingestion, dermal absorption, or inhalation of volatile organic compounds released from surface water.
>
> Soil: Exposures to contaminants in soil could occur as a result of direct contact with soil and subsequent incidental ingestion or dermal absorption of these contaminants. Chemicals released from the soil into the air could also be a pathway of concern if the chemicals were subsequently inhaled.
>
> Food Chain: Exposures to chemicals could also occur as a result of ingestion of produce, fish, or game in which site-related chemicals may have bioaccumulated (e.g., PCBs) or upon which such chemicals could have been deposited.

Based on the list of exposure pathways, a screening process should be performed to determine which pathways should be evaluated in detail in the risk assessment. This screening process has not been precisely described in EPA guidance manuals but should be based on consideration of several important factors. These include whether there is sufficient data to evaluate exposure, the frequency and duration of likely exposures, and the relative contribution of the exposure to the total site risk.

The number of pathways ultimately selected for detailed evaluation in a risk assessment varies depending upon site-specific conditions such as accessibility and availability of sampling data. In general, anywhere from two or three to ten or more pathways may be selected for detailed evaluation. In some cases, it will be extremely difficult to quantitatively evaluate a potentially important pathway due to inadequate sampling data and the availability of adequate fate and transport models. In these cases, it may be appropriate to qualitatively evaluate the pathway in the risk assessment. It may also be appropriate to obtain additional site information or data to further evaluate potential pathways of concern. This may be done as part of a phased Remedial Investigation effort.

4.2 ESTIMATION OF EXPOSURE POINT CONCENTRATIONS

The exposure point concentration refers to the amount of chemical in an environmental medium to which one may be exposed (i.e. the measured concentration in the medium of concern). The exposure point concentration is usually expressed in units of mass per unit volume (mg/l or mg/m^3) or mass per unit weight (mg/kg). Exposure point concentration should be differentiated from the term exposure dose - a term used to describe the resulting exposure from a particular concentration, expressed in units of mg/kg/day (see Section 4.3).

Average and maximum chemical concentrations (exposure point concentrations) should be developed for each exposure pathway based on site sampling data or on modeling results. The sampling data used to characterize exposure point concentrations should be representative of the specific exposure pathway of concern. In some instances (if there is a discrete "hot spot" of contamination or if there are separate areas where different exposures are expected), it may be appropriate to identify exposure point concentrations for discrete areas of a site. In this case, a single exposure pathway may be evaluated more than once using exposure point concentrations derived from different portions of the site sampling data.

4.3 ESTIMATION OF EXPOSURE DOSE

To quantitatively estimate the risk posed by the presence of one or more contaminants in an environmental medium, one must estimate the exposure dose of each contaminant. The exposure dose is similar to the administered dose of a laboratory experiment from which cancer potency factors and reference doses are usually derived.

Other terms important to understand include absorbed dose, metabolized dose, and body burden. Each of these terms relate the exposure dose to a particular biological function. The absorbed dose corresponds to the amount of the exposure dose that is absorbed either through the skin, the gastrointestinal tract, or the lungs. Similarly, the metabolized dose describes the amount which is metabolized. The metabolized dose is an important parameter when the toxic compound is thought to exert its toxic effects via a metabolite.

Finally, the body burden is used to describe the level of a particular compound in a biological tissue or fluid. It is influenced by the exposure dose, absorption, metabolism, and excretion. The body burden is ideally the best measure of exposure to contaminants. Such measurements are however, beyond the scope of CERCLA risk assessments in which data describing exposure point concentrations is usually all that is available. Thus estimation of exposure dose forms the basis for the quantitative risk assessment process.

The general equation that may be used to calculate an exposure dose is the total amount of chemical exposure divided by body weight and the period over which exposure is to be averaged. The exposure dose is also normalized by the use of a relative absorption factor (RAF) which takes into account differences in absorption between the medium and the exposure route of concern, and the medium and exposure route used in the laboratory study from which the cancer potency factor or reference dose was derived. The total amount of chemical exposure is estimated from information on the chemical concentration in the environmental medium of concern, the frequency and duration of exposure, and the magnitude of exposure to the medium of concern. Thus the general equation for computing the exposure dose is as follows:

$$EXP_i = \frac{(C_m)(M_m)(F)(D)(RAF_{mi})}{(BW)(AVG)(365\ \text{days/year})}$$

where

EXP_i = average daily exposure dose for pathway i (normalized) (mg/kg/day)

C_m = chemical concentration in medium m (e.g., mg/kg)

M_m = magnitude of exposure to medium m per day of exposure (e.g., kg/day of exposure)

F = frequency of exposure (days of exposure/yr)

D = duration of exposure (yrs)

RAF_{mi} = relative absorption factor for medium m and pathway i (unitless)

BW = body weight (kg)

AVG = number of years over which exposure is averaged (70 years for carcinogenic effects, D for noncarcinogenic effects)

In estimating exposure doses, the time over which the total dose is averaged differs when assessing carcinogenic and noncarcinogenic effects as discussed in Section 5.0. For carcinogenic effects, the total dose is averaged over a 70 year lifetime and over 365 days per year to yield an average daily lifetime dose. For noncarcinogenic effects, the total dose is averaged over the total period of exposure (i.e. 10 years) and over 365 days per year. This yields an average daily dose for the period of exposure. Representation of exposure dose in these terms facilitates future estimates of lifetime cancer risk and hazard indices.

For noncarcinogenic effects, the standard averaging approach is most appropriately applied to exposure scenarios in which the frequency of exposure is high, such as several times a week throughout the entire year. For infrequent exposures, this approach may not accurately represent the potential for acute health effects. The implicit assumption to dose averaging is that a high dose over a short period of time is toxicologically equivalent to a low dose over a longer period of time. For many contaminants, acute or subchronic effects may occur from a single high dose or a limited number of moderately high doses. Averaging the total dose over an entire year may thus be inappropriate if it is anticipated that such acute noncarcinogenic health effects may occur. In this case, the risk assessor should evaluate the exposure dose incurred over a short period of time (such as a single exposure event) by making the necessary adjustments to F, D, AVG, and 365 days in the general exposure dose equation. The risk assessor should then compare this exposure dose to a health based criterion that is derived for a shorter exposure period such as a one or ten day Health Advisory.

For some exposure pathways, such as incidental ingestion of soil, the bioavailability of the chemical from the environmental medium to which an individual is exposed should be taken into account as chemicals present in a soil matrix may be less bioavailable than chemicals present in a solvent or in water. The relative absorption factor (RAF) is defined as the ratio of the estimated absorption factor for the site-specific medium and route of exposure to the known or estimated absorption factor from the laboratory study from which the cancer potency factor or the reference dose was derived. The use of this factor allows the risk assessor to make appropriate adjustments to the assessment if the efficiency of absorption is known or expected to differ because of physiological, matrix, or vehicle effects. Relative absorption factors for each contaminant in each medium for each exposure pathway should be derived from the literature. However, due to a lack of data on the absorption of contaminants from soils, Region I has listed some default values for this pathway in Section 4.7.1 and 4.7.2.

To the extent possible, EPA Region 1 has standardized the exposure parameters that should be used in risk assessments prepared for the Regional Office. These parameters (primarily for soils) are presented in the appropriate exposure sections. Each of the exposure parameters contained in this guidance are subject to some inherent uncertainty as a result of limited experimental data and due to variability in individual activity patterns. While these values have some uncertainty in them, it was the feeling of the Region I Office that in order to afford consistency across risk assessments, it was advantageous to specify parameters to the extent possible. The Regional Office intends to reevaluate these parameters as new information becomes available. However until such time, they are to be used in risk assessments prepared for the Region I Office. The risk assessor should identify the limitations of this method in the risk assessment as these values will ultimately influence the risk estimate and the selection of target clean-up levels.

4.4 DEVELOPING EXPOSURE SCENARIOS

Exposure scenarios are developed to simulate possible exposures in the absence of site specific exposure information and to account for the variability in contaminant distribution and land use. Usually there are two levels to consider in developing exposure scenarios. The first involves identifying present and future potential exposure scenarios. Much of this task involves the identification of present and future land and water use at a site and at adjacent properties and identification of populations of concern. Present exposure scenarios are thus fairly easy to identify though as a word of caution, present exposure scenarios include those that have a present potential of occurring as well as those known to occur. Future exposure scenarios are often more difficult to identify though Region I has maintained the position that future land use at most Superfund sites could be residential. Any deviations from a residential future exposure scenario should be approved by the EPA risk assessment specialist prior to proceeding with the development of the exposure assessment. The outcome of the first level of exposure scenario development should thus identify potential receptor populations and their exposure pathways to contaminated media considering both present and potential future land use. It is therefore not uncommon to identify some exposure scenarios as only being a future potential exposure scenario (i.e., ingestion of ground water) or to have more than one exposure scenario for a particular medium (i.e., present exposure to soils for adults and present exposure to soils for children).

The second level in developing an exposure scenario involves the estimation of a range of conditions characterized by an "average case" and a "reasonable worst case" exposure scenario for each selected exposure pathway. The "average case" exposure scenario combines average values for exposure point concentrations with reasonably conservative exposure assumptions from the sections that follow. Exposures represented by this scenario may reasonably be assumed to occur. However, the actual level of risk described by the "average case" exposure is likely to be lower than the value reported due to the use of conservatively derived health criteria. The "reasonable worst case" exposure scenario combines maximum values for exposure point concentrations with the reasonably conservative parameters applied to the "average case" estimate. The reasonable worst case scenario is intended to provide an upper bound of the possible risk.

In selecting exposure parameters, (i.e., ingestion rate, relative absorption factor, body weight) the same parameter value should be used for both the average and the reasonable worst case exposure scenarios except for contaminant concentration Many of these parameter values are specified in the exposure sections that follow recognizing that certain parameters (ingestion rate, body weight, and exposure duration) may vary from scenario to scenario according to the population (adult vs. child) and land use (residential vs. industrial) for a given site. Values for the frequency and duration have not been specified in the guidance but should be determined on a case-by-case basis. Once determined, the same frequency and duration of exposure should be applied to both the average and reasonable worst case scenarios. Only when considering present vs. future exposures is there room for flexibility in the values assigned to exposure frequency and duration. Because frequency of exposure is very site specific, the risk assessor should carefully consider the size and location(s) of contaminated area(s) described by the average and maximum contaminant concentrations. Additionally, it is in the risk assessor's best interest to conduct a site visit to gain a better understanding of the site and potential exposure scenarios.

4.5 EXPOSURES VIA GROUNDWATER

There are several routes of exposure to contaminants that may be present in groundwater. These include: (1) direct ingestion of groundwater; (2) inhalation of chemicals released into indoor air as a result of household water use; (3) dermal absorption of chemicals from household water use; and (4) groundwater seepage into basements and subsequent volatilization into indoor air. Indirect pathways of exposure could also occur if contaminated groundwater is used to irrigate gardens and contaminants are subsequently deposited on or accumulated in food crops.

4.5.1 INGESTION OF GROUNDWATER

Exposures via ingestion of groundwater are almost always evaluated in a risk assessment. Exposures can be evaluated under both present site use conditions (e.g., nearby residents with contaminated well water) and under future use conditions (e.g., residential exposure could occur if no remediation were to take place at the site). It is the approach of Region I to use standardized exposure assumptions for the drinking water ingestion rate (2 l/day) and in the absence of any data, a relative absorption factor of 100% for all chemicals. It is assumed that a potentially exposed individual may be exposed every day over a 70-year lifetime though there may be instances in which a less-than-lifetime exposure assessment may be relevant. Approval to conduct a less-than-lifetime exposure for this pathway should come from the Region I risk assessor prior to conducting such an analysis. As mentioned above, exposures are usually estimated for both an average case exposure scenario and a reasonable worst case exposure scenario. For the average case, an average contaminant concentration in groundwater may be used whereas for the reasonable worst case, the maximum detected concentration may be used. In either case, the sample data should be carefully evaluated to determine which data (e.g. deep vs. shallow monitoring wells, individual wells vs. aquifer-wide contamination) are most appropriate for this pathway.

4.5.2 INHALATION OF VOLATILIZED CONTAMINANTS FROM HOUSEHOLD WATER USE

Some chemicals present in groundwater may be highly volatile and as a result may readily be released into indoor air during common uses of household water supplies. Such uses of water include showering, dish washing, laundering, and bathing. Although researchers have estimated that inhalation of volatile organic chemicals released from water into indoor air may present risks comparable to those associated with ingestion of groundwater (Andelman 1985, Foster and Chrostowski 1987), exposure models that could quantitatively predict such exposures have not been extensively validated. This exposure pathway should be evaluated either qualitatively or quantitatively if VOCs are present in domestic water supplies.

4.5.3 DERMAL ABSORPTION FROM HOUSEHOLD WATER USE

Some chemicals present in groundwater could potentially be absorbed as a result of dermal contact with tap water (e.g., while bathing). In general, the magnitude of potential exposures via dermal absorption is very low due to the short duration of skin contact (e.g., on the order of minutes), and the low permeability of the skin to compounds that may be present at dilute levels in tap water (e.g., volatile organic compounds). For most risk assessments, this exposure pathway need not be quantitatively evaluated.

4.6 EXPOSURES VIA SURFACE WATER

Exposures to chemicals present in surface water may occur as a result of: (1) incidental ingestion while wading or swimming; (2) inhalation of volatilized contaminants released from surface water; and (3) dermal absorption while wading or swimming. Indirect pathways of exposure could also occur, for example, if contaminated surface water is used to irrigate home produce gardens and contaminants are subsequently bioaccumulated into produce.

4.6.1 INCIDENTAL INGESTION OF SURFACE WATER

Depending upon site specific conditions, incidental ingestion of contaminated surface water may be a concern to human health. Information describing the potential amount of surface water ingested while swimming is available (50 ml per 1 hour swimming event) (EPA 1988), although a rigorous experimental study examining this parameter has not been conducted. The amount of surface water ingested as a result of wading is probably minimal, though there is limited scientific information available regarding this parameter. For either a swimming or wading scenario however, the uncertainty in the incidental ingestion rate should be recognized. Values describing the frequency and duration of potential ingestion exposures should be developed based on site-specific population activity patterns. Chemical concentrations at the potential exposure points should be based on the sampling data set most relevant to the pathway being evaluated.

4.6.2 INHALATION OF VOLATILIZED CONTAMINANTS FROM SURFACE WATER

Surface water sampling results may indicate high levels of volatile organic compounds, such as trichloroethylene, vinyl chloride, and tetrachloroethylene, in surface water (e.g., impoundments, streams, lagoons). These compounds will volatilize to some extent into the air and potentially be transported downwind to nearby receptors. Depending upon site-specific conditions (e.g., configuration of surface water body, contaminant levels in surface water, surface water temperature), this exposure pathway may be selected for detailed evaluation in the risk assessment. Volatilization models are available for quantifying the potential emissions of volatile organic compounds from surface water, (Lyman et al.1982). In addition, air dispersion models are available for estimating potential downwind concentrations (e.g., area or line source models). On occasion, air sampling protocols may be designed to reflect emissions of volatile organic compounds from surface water. Again, the frequency and duration of exposures for this exposure pathway should be based on site-specific population activity patterns.

4.6.3 DERMAL ABSORPTION WHILE WADING OR SWIMMING

If surface water bodies known to be frequently used for swimming contain chemicals of concern (e.g., pesticides, PCBs), this exposure pathway may be selected for detailed evaluation. In deriving a relative absorption factor for the dermal absorption of contaminants from surface water, several approaches may be used to estimate the extent to which chemicals present in surface water may be absorbed into the body. Chemical-specific information may be available which describes the fraction of a contacted chemical that may be absorbed. In using this approach, careful consideration must be given to the selection of the volume of water which is assumed to come in contact with the skin surface. Alternatively, chemical-specific data may describe the rate of chemical absorption from water through the skin (flux rate). There is little information available which describes the absorption of any chemical from dilute aqueous solutions (i.e., the usual exposure situation at a site); most experimental work has been conducted with pure compounds or highly concentrated solutions. Thus, there is a great deal of uncertainty associated with estimates of dermal uptake from water.

In the absence of chemical-specific dermal absorption data, information on one chemical may be used for other chemicals with similar chemical and physical properties (e.g., data on PCDDs/PCDFs may be used for PCBs and PAHs). In the absence of any information, the chemical could be assumed to be absorbed at the same flux rate as the flux rate for water.

The frequency and duration of exposure for this pathway should be estimated based on site-specific population activity patterns. As with the other exposure pathways mentioned above, there are uncertainties in the parameters used to estimate dermal exposures from surface water.

4.7 EXPOSURES VIA SOILS

There are several exposure pathways to consider when assessing soil contamination. These include: dermal absorption, ingestion, and inhalation of either volatile chemicals released from soil or soil particulates. Several indirect exposure pathways which should also be considered include the ingestion of contaminated agricultural products, livestock, or aquatic organisms which have bioaccumulated contaminants from the soil.

4.7.1 DERMAL ABSORPTION OF CONTAMINANTS FROM SOILS

Exposure to contaminants via direct contact with contaminated soils and subsequent absorption through the skin can be an important route of exposure at hazardous waste sites. The importance of this pathway is a function of the contaminant concentration in soil, the extent, frequency, and duration of soil contact, and the behavior of the contaminant once introduced onto the skin. A general equation that may be used to estimate contaminant doses from dermal exposure to contaminants in soils is:

$$EXP_d = \frac{C_s \times SCR \times F \times D \times RAF_{sd}}{BW \times AVG \times 365\ \text{days/year} \times 10^6\ \text{mg/kg}}$$

EXP_d = average daily exposure dose for the dermal pathway (mg/kg/day)
C_s = contaminant concentration in soil (mg/kg)
SCR = soil contact rate (mg/day of exposure)
F = frequency of exposure (days of exposure/yr)
D = duration of exposure (years)
RAF_{sd} = relative absorption factor for soil contaminants via the dermal pathway (unitless)
BW = body weight (kg)
AVG = number of years over which exposure is averaged (70 yrs for carcinogenic effects and D for noncarcinogenic effects)

Parameters that should be used for dermal contact with soils are discussed below.

Contaminant Concentration in Soils (Cs): Soil contamination at a hazardous waste site is often unevenly distributed across the site and with soil depth. It is not uncommon to have separate areas of contamination ("hot spots" or different contaminants) at a site. The soil data may indicate that a range of exposure scenarios and concentrations are necessary to adequately assess direct contact exposure at a site. Therefore, analytical data should be evaluated carefully to identify whether hot spots or special areas of contamination exist. If so, these areas should be discussed in the exposure assessment and, if possible, assessed separately to avoid either under or over estimating potential exposure point concentrations. In addition, surface soil data should be used to estimate exposure concentrations for present exposure scenarios. If it is likely that either present or future exposure to sub-surface soils is possible, then the extent of sub-surface soil contamination should be used in generating estimates of potential exposure dose.

Other factors to consider when evaluating soil data include the presence of naturally occurring inorganic contaminants and the variability inherent in analyzing extractable compounds from a soil matrix. Background concentrations of some metals (As, Ni, etc.) can be quite high. A decision to include these data should be made with the EPA site manager and the EPA risk assessment specialist.

Soil Contact Rate (SCR): After evaluating the literature, the Region I Office has established a soil contact rate that should be used for normal residential and recreational activities of 500 mg/day of exposure. This value is based on a soil deposition rate of 0.5 mg/cm^2, a potentially exposed skin surface area of 2,000 cm^2, and a factor of 50% to account for the fraction of the total skin surface area that is likely to actually be exposed. The deposition rate of 0.5 mg soil/cm^2 was obtained as a reasonable estimate from review of the literature. The total surface area of 2,000 cm^2 roughly corresponds to the hands, forearms, feet, and lower legs of a young child or to the hands and feet of an adult. A value of 50% has been included to account for the fact that it is unlikely that the total surface area described above would be covered with soils. In the event that gardening is an exposure of concern, the soil contact rate should be increased to approximately 1,000 mg/day of exposure and the risk assessor may wish to consider acute or subchronic exposure dose and health effects depending on the frequency and duration of the exposure.

Relative Absorption Factor (RAF_{sd}): The relative absorption factor for soil contaminants via the dermal pathway of exposure refers to the fraction of a chemical which after contact, is likely to be absorbed through the skin relative to the absorption of the compound in a laboratory study from which the cancer potency factor or reference dose was derived. Contaminants adsorbed onto soils and sediments are presumed to be less available for dermal absorption than pure compounds or solutions. To account for these differences, the Regional Office has listed below the relative absorption factors that can be used for assessing dermal absorption of contaminants from soils when data on dermal absorption from soils is not available. The relative absorption factors that can be used for dermal contact with soils are as follows:

Volatile Organic Compounds:	50%
Semivolatile Organic Compounds	
PAHs:	5%
PCBs:	5%
Pesticides:	
-high sorption to soils: (e.g., chlordane, DDD, DDT)	5%
-low sorption to soils: (e.g., lindane, acrolein)	50%
Inorganics:	negligible

As with the other exposure pathways, frequency of contact tends to be very site specific and often less-than-lifetime exposures are of concern. When the frequency and duration terms fall much less than daily and a lifetime respectively, careful consideration should be given to the time period over which the dose is averaged.

4.7.2 INGESTION OF CONTAMINATED SOIL

Exposure to contaminants through the ingestion of soil can result from the inadvertent consumption of soil adhering to the hands, food items, or objects that are placed into the mouth, or the intentional ingestion of soil (commonly referred to as pica behavior). The exposure dose for this pathway can be estimated from the concentration of the contaminant in the soil and the amount of soil ingested per exposure event. The resulting exposure dose can be compared to quantitative dose-response data by the use of a relative absorption factor (RAF) that corrects for differences in gastrointestinal absorption between soil and usual laboratory vehicles. The general equation for evaluating soil ingestion exposures is:

$$EXP_{si} = \frac{C_s \times SI \times F \times D \times RAF_{si}}{BW \times AVG \times 365 \text{ days/year} \times 10^6 \text{ mg/kg}}$$

EXP_{si} = average daily exposure dose for the ingestion pathway (mg/kg/day)
C_s = contaminant concentration in soil (mg/kg)
SI = soil ingestion rate (mg/day of exposure)
F = frequency of exposure (days of exposure/yr)
D = duration of exposure (years)
RAF_{si} = relative absorption factor for soil contaminants via ingestion pathway (unitless)
BW = body weight (kg)
AVG = number of years of exposure (70 years for carcinogenic effects, D for noncarcinogenic effects)

Contaminant Concentrations (Cs): The contaminant concentration in the soil should be estimated from the analytical data. Usually, the same contaminant levels used to assess exposure via dermal absorption from soils can be used to assess exposure via the ingestion of soil. In addition to the considerations given to the data evaluations for assessing direct contact exposure (e.g., "hot spots"), contaminant levels representative of areas where young children are likely to play (e.g., yards, playgrounds) should also be evaluated. Two exposure scenarios should be evaluated, based on the average and maximum soil concentrations.

Soil Ingestion Rate (SI): A recent directive from EPA Headquarters/OSWER Directive 9850.4) has identified the following soil ingestion rates that are to be used according to the age and population of concern. Young children between the ages of 1-6 years may engage in a lot of hand to mouth activity which can result in the ingestion of a considerable amount of soil. When the exposure of concern centers on this age group, the EPA Headquarters has identified a soil ingestion rate of 200 mg/day of exposure. Because older children (greater than 6 years) and adults also may inadvertently ingest soil, the soil ingestion rate to be applied to the age groups is 100 mg/day of exposure. When the exposure of interest is for a full 70 year lifetime (as may be the case for a future residential exposure scenario), it is appropriate to use a single lifetime soil ingestion rate of 100 mg/day of exposure.

Because pica (excessive ingestion of non-food objects) is an unusual condition, the pica exposure should only be evaluated when there is an indication that pica behavior is relevant to a specific site. A value of 5,000 mg/day is considered a reasonable estimate of a maximum single-day soil ingestion rate for a child with habitual pica.

Relative Absorption Factor (RAF_{si}): The bioavailability of chemicals adsorbed on ingested soils affects the amount of contaminant exposure. When evaluating the ingestion of contaminated soils, a relative absorption factor should be used to account for the differing bioavailability between the contaminant in the soil matrix and the contaminant in an experimentally administered medium such as solvent or food. The relative absorption factors for the ingestion of contaminants in soils that can be used for Region I risk assessments in the absence of any data are as follows:

Volatile Organic Compounds:	100%
Semivolatile Organic Compounds	
PAHs:	100%
PCBs:	30%
Pesticides	
-high sorption to soils: (e.g., chlordane, DDD, DDT)	30%
-low sorption to soils: (e.g., lindane, acrolein)	100%
Inorganics	
lead:	
adults:	30%
children (age 1-6):	50%
all other inorganics:	100%

Frequency of soil ingestion should be site specific as should be the exposure duration. Additionally, frequency and duration values may vary depending on present and future land usage. Values selected for frequency and duration of the ingestion of soils should be consistent with the same parameters selected for dermal contact with soils.

4.8 INHALATION OF CONTAMINANTS

The assessment of airborne contaminants should consider several pathways of exposure. Pathways to consider include those associated with the release of contaminants directly into the air as well as pathways resulting from the transport of contaminants to the atmosphere through either soils or groundwater.

Quantification of air impacts is limited by variability in emission rates, varying meteorological and climatic conditions, and often by a lack of actual monitoring data or standardized sampling and analytical protocols. Such limitations generally place severe constraints on the degree to which the available data can provide an adequate basis for estimating inhalation exposure impacts. The following discussion should aid the risk assessor in determining the nature and scope of the exposure assessment for airborne contaminants.

4.8.1 IDENTIFICATION OF EXPOSURE PATHWAYS

The identification of inhalation pathways should consider the evaluation of both on and off-site exposures. Within each category, several exposure scenarios should be considered. Examples of exposures occurring on-site include scenarios such as walking or hunting on or near source areas. Inhalation exposure in this case may arise owing to characteristic passive behaviors. More active on-site activities such as dirt biking, car driving, and swimming, in which source areas may be disturbed, may result in increased inhalation exposures to site contaminants. Off-site exposures may also occur by virtue of pollutant transport and atmospheric dispersion from on-site source areas. Other inhalation pathways to consider involve the volatization of contaminants which have migrated off-site via soil or water. Volatilization may occur either in the outdoor air or the indoor air of residences and other buildings.

Selection of the important inhalation exposure pathways for further evaluation will depend on the availability of data and knowledge of the human activity patterns which are unique to each site. Activity patterns determine many important exposure parameters such as the frequency and duration of exposures and the magnitude of those exposures. At a minimum, the air pathway of exposure should be evaluated qualitatively. If air data is unavailable and yet the inhalation pathway is of concern, then attempts to collect additional data should be exhausted prior to conducting a qualitative assessment.

When quantitatively assessing the inhalation exposures to residents living on or near a Superfund site, indoor exposure (i.e. water supply) concentrations are assumed to be the same as outdoor concentrations, unless data show that there is an indoor contamination source or that there is a selective partitioning of contamination between indoor and outdoor environments. Indoor exposures such as those resulting from volatilization of contaminants from household water supplies should be considered on a case-by-case basis (see exposures via groundwater). In circumstances where there is information to indicate that dirt biking, swimming or other activities which disturb source areas may be frequent activities with the potential for inhalation exposures, then these scenarios should also be considered further (see exposures via surface water and soil).

4.8.2 ESTIMATION OF EXPOSURE POINT CONCENTRATIONS

Generally, most exposure assessment techniques employ a combination of monitoring and modeling in predicting exposure concentrations. In estimating exposure point concentrations, monitored values are preferred over modeled values however, the two techniques are often used together to predict long term concentrations or concentrations at a given receptor location. The Air/Superfund National Technical Guidance Study Series provides guidance on developing baseline emission estimates (Volume II, Estimation of Baseline Air Emissions at Superfund Sites) and dispersion modeling using baseline emissions to predict ambient concentrations at locations of concern (Volume IV, Procedures for Dispersion Modeling and Air Monitoring).

For the purpose of the risk assessment, air monitoring information must be specific, providing an ambient level for each chemical of concern. Several monitoring methods for VOCs such as the HNu and OVA, when operated in the survey mode, merely give a total hydrocarbon value and are not suitable for the purpose of the risk assessment. In order to collect chemical specific information on VOCs at the level of sensitivity needed for a risk assessment, some sort of gas chromatography (GC) is advised, preferably coupled to a mass spectrometer (MS). The GC coupled to a MS provides the most reliable data and is thus the method of choice for volatile organic compounds. Several common instruments currently 2available which provide GC capability are the OVA set in the GC mode, the Photovac, and the use of a sophisticated laboratory GC.

Monitoring approaches are used to provide empirical estimates of pollutant concentrations at specific times and under specific meteorological conditions. Monitoring approaches have an advantage over modeling approaches in that they provide exposure estimates based on direct measurements, and therefore, may provide a better approximation of actual exposure at a site. Thus, preference is generally given to monitored values over modeled values, as long as the determination can be made that the location, sampling frequency, and the sampling and analytical procedures can provide reasonable estimates of the worst case and long-term average air quality impacts.

Other methods used in ambient air monitoring include a modified Hi-Vol method for semi-volatile organic compounds (PCBs, pesticides) and the Hi-Vol filter for large particles and metals. For sampling particles less than 10 um in diameter, the EPA Reference method for PM_{10} should be followed. On questions pertaining to air monitoring, Peter Kahn (860-4392) at EPA's Lab in Lexington, and the EPA Compendium of Methods for the Determination of Toxic Organic Compounds in Ambient Air (EPA 1984), should be consulted.

Because the atmosphere is in a constant state of flux, several points should be considered in designing and interpreting monitoring studies.

1) Monitors should be placed in locations such that the impacts of up-wind sources of air pollution can be differentiated from impacts related to the site in question. One must be able to distinguish between contaminants originating from the site and those that originate from other sources.

2) Implicit in the above task is the need to obtain on-site meteorological information (temperature, wind velocity, wind direction, pressure, etc.) both before and concurrent with sample collection. Site specific meteorological data is also valuable if any modeling of pollutant concentrations is planned.

3) Consideration should be given to the time period over which samples are collected to facilitate comparison to standards and to generate data that is as representative of the site as possible. The sampling method should also generate data that is of concern from the public health professional's perspective (e.g. inhalable particulates vs. total suspended particulates).

Modeling approaches usually rely on assumptions regarding emission rates for selected compounds and/or on estimated dispersion factors in order to project air quality impacts at various receptor locations. Different modeling approaches are required to estimate short-term and long-term average air quality impacts. Estimates of model input parameters should reflect as closely as possible the actual conditions at the site; however, if the available database is inadequate to characterize the site, model inputs should be selected so as to provide reasonable assurance that the actual air quality impacts are likely to be below the modeled values.

Many of the models developed by EPA are dispersion models designed to predict impacts from large point sources and thus have limited application to the Superfund program. The National Technical Guidance Study Series should be consulted for more information. Models are also described in the Superfund Exposure Assessment Manual (EPA 1988). Regardless of the model selected, consultation with the EPA Region I Air Management Division is strongly recommended to insure that the correct model is applied to the situation at hand.

4.8.3 ESTIMATION OF EXPOSURE DOSE

The general equation that has previously been described for estimating exposure dose holds true for air exposures as well. The equation for the average daily exposure dose over the period of exposure in mg/kg/day is:

$$EXP_i = \frac{(C_a)(IR)(F)(D)(RAF_{ai})}{(BW)(AVG)(365\ \text{days/year})}$$

where:

EXP_i = average daily dose for the inhalation pathway (mg/kg/day)
C_a = concentration of contaminant in air (mg/m^3)
IR = inhalation rate (m^3/day)
F = frequency of exposure (days/yr)
D = duration of exposure (yrs)
BW = body weight (kg)
RAF_{ai} = relative absorption factor for airborne contaminants via the inhalation pathway
AVG = number of years over which exposure is averaged (70 years for carcinogenic effects, D for noncarcinogenic effects)

This basic equation holds true for both particulates and VOCs. The major differences in this equation from the general exposure equation already presented are the units for contaminant concentration (mg/m^3) and the magnitude of exposure to the medium (inhalation rate), which is expressed in terms of m^3/day. Inhalation exposures present some interesting aspects when it comes to determining contaminant concentration. By virtue of the methods used to collect ambient air samples (or to model concentration), there is a measure of time associated with the concentration term for this pathway of exposure. Because time is a factor in the concentration, this pathway lends itself to the evaluation of both acute and chronic exposures and thus health effects. Sample concentrations collected or predicted over an 8 or 24 hour time period readily lend themselves to the evaluation of acute health effects. In contrast, samples concentrations predicted for a year or more lend themselves to an evaluation of chronic exposures and thus chronic health effects. Thus, this pathway often leads to a more extensive evaluation of exposure dose than is possible for other exposure pathways.

Standard exposure parameters for an adult's inhalation rate and body weight are 20 m^3/day and 70 kg, respectively. When assessing the risks to small children, specific populations, or to individuals engaged in certain activities with high inhalation rates, other values may be more appropriate for inhalation rate and body weight (see EPA 1985). In the absence of any data, the relative absorption factor for the inhalation pathway can be assumed to be 100% for all contaminants evaluated. The estimated frequency and duration of exposure should always consider continuous lifetime exposure (24 hrs/day, every day for 70 years) at a minimum. Additionally, if the exposure, health effects, and data warrant, a less than lifetime exposure dose can also be evaluated.

5.0 RISK CHARACTERIZATION

Risk characterization defines the present and potential threats to human health posed by the contaminants at a Superfund site. The site-specific risks are characterized by integrating the data developed from the hazard identification (Section 2.0), dose-response assessment (Section 3.0), and exposure assessment (Section 4.0) portions of the risk assessment. In characterizing and presenting such risks, carcinogenic and noncarcinogenic health risks are described for both present and future potential exposures and for both average and reasonable worst case exposure scenarios. The results of the risk characterization are often used to establish the need for risk reduction which is subsequently addressed in the Feasibility Study.

This section of the Region 1 guidance document describes the methods and approaches to be used in the risk characterization. It discusses methods for characterizing the noncarcinogenic and carcinogenic risks at Superfund sites (Section 5.1), obstacles to the evaluation of risk (Section 5.2), and finally the risk summary (Section 5.3).

5.1 NONCARCINOGENIC AND CARCINOGENIC RISK CHARACTERIZATION

The underlying principle of every risk characterization is that risk is a function of both exposure and chemical toxicity. This principle is often described by the following relationship:

$$\text{Risk} = F\ (\text{exposure, toxicity})$$

Since risk is a function of both exposure and toxicity, both must be present to have a risk. Therefore, if either exposure (present or future potential) or toxicity are absent, then there is not a basis for characterizing risk. This basic relationship applies to the assessment of both noncarcinogenic and carcinogenic risk.

The exposure term in the risk equation is calculated as discussed in the exposure assessment (Section 4.0) in which both present and possible future exposures are considered. The toxicity term in the above equation is a function of both the hazard identification (Section 2.0) and dose-response assessment (Section 3.0). For many of the known and suspect human carcinogens, EPA's cancer potency factors are to be used to describe toxicity. For noncarcinogenic effects, the preferred indicator of toxicity is the reference dose (RfD). In the absence of a reference dose, other standards and criteria can be used (see Section 3.2).

5.1.1 NONCARCINOGENIC RISK EVALUATION

The noncarcinogenic risk evaluation refers to the process in which the potential for noncarcinogenic health effects manifesting themselves are characterized. Noncarcinogenic risk evaluation is based on a threshold response theory. Consequently, the process of noncarcinogenic risk evaluation involves a comparison of an exposure level to the estimated threshold response level which usually has incorporated in it, a margin of safety (see discussion of reference dose in Section 3.2.1.1). The "Hazard Index" is the term that has been coined to described this relationship and it is described in the sections that follow.

5.1.1.1 The Hazard Index (HI)

The Hazard Index is a numerical representation of the potential for noncarcinogenic health effects manifesting themselves (risk). Consequently, the derivation of the Hazard Index should be performed for both noncarcinogenic compounds and carcinogenic compounds with noncarcinogenic health effects. The Hazard Index is computed by dividing the exposure dose by the reference dose for an individual chemical. In the absence of a reference dose, other suitable health based values may substitute (see Section 3.2).

$$\text{Hazard Index} = \frac{\text{Exposure Dose (mg/kg/day)}}{\text{RfD (mg/kg/day)}}$$

Because we assume response additivity, the HI should be summed within each pathway of exposure for all noncarcinogenic effects that are the same or similar with respect to toxicity endpoint. As a matter of convenience, the HI is often summed for a pathway for all noncarcinogenic effects regardless of the similarity of their toxic endpoints. Summation of the HI values in this fashion is acceptable if the resulting HI is less-than unity (one). However, if the resulting summation exceeds unity, the HI analysis should be refined such that only those chemicals which exhibit the same or similar toxicity endpoint are evaluated collectively. Since compounds may display a variety of effects depending on concentration, the toxic endpoint is defined as the most sensitive noncarcinogenic health effect used to derive the reference dose or other suitable health based criteria.

As an example, the HI for chemicals A, B, and C, whose RfD and target endpoint are based on liver histopathology, should be added together. The HI for chemicals D, E, and F, whose RfD and target endpoint are based on hematopoietic effects, should be added together. However, the HI from A, B, and C (liver effects) should not be added to HI from D, E, and F (hematopoietic effects).

5.1.1.2 Less-Than-Lifetime Exposure

Actual and potential chemical exposures at Superfund sites are often less-than-lifetime in duration. For instance, an exposure scenario for dermal contact to contaminated soil by children may be identified as only 5 to 10 years in duration. For noncarcinogenic effects, it is the preference of the Regional Office to average the less-than-lifetime dose over a single year of exposure rather than over a 70 year lifetime. Thus the term for the averaging period (AVG) in the denominator of the exposure dose equation in Section 4.3 becomes something less than 70 years. The resulting dose estimate is then compared to an EPA verified reference dose (RfD) or other suitable dose-response value. The following discussion presents several issues that the risk assessor may wish to recognize in the risk characterization section for less-than-lifetime exposures.

In the absence of a subchronic reference dose or other suitable subchronic criterion, chronic reference doses can be used to evaluate the potential for noncarcinogenic health effects from a less-than-lifetime exposure. The result is that the Hazard Index calculated for a subchronic exposure scenario is the same as one calculated for a scenario that assumes a lifetime of exposure to the same contstant daily dose. This leads to a conservative representation of risk. The risk assessor may wish to discuss the implications of these conservative assumptions when interpreting the HI for a subchronic exposure calculated in this manner in the risk characteriztaion section.

When an exposure becomes much less than a lifetime or is very infrequent in nature, the risk assessor should carefully consider the potential for acute health effects. As an example, when lead is a contaminant of concern in soils, often a chronic yet infrequent exposure is identified and the risk assessor should be concerned about the potential for acute health effects. In these instances, the reference dose is not the suitable criterion for computing a Hazard Index, rather a 1-day or 10-day health advisory is more relevant. Additionally, the exposure dose should be tailored to the acute effect and exposure period of concern (i.e. compute dose for a single day of exposure.)

5.1.1.3 Interpretation of the Hazard Index

Like the incremental cancer risk estimates, the Hazard Index describes an incremental level of concern for the noncarcinogenic effects; that is, only the Hazard Index for site-related chemicals and exposures is computed. It is usually beyond the focus of Superfund risk assessments to consider the risk for chemicals and exposures that can not be attributed to the site in question.

When an HI as computed in the preceding sections is less than one, then adverse health effects from exposures attributed to the chemical(s) at the site are not anticipated. This is true by virtue of the definition of a reference dose. "The RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime."

When the HI exceeds one for either a single compound or for several compounds exhibiting similar toxic endpoints, then further discussion is needed considering the nature of the relevant toxicity endpoint, the quality of the toxicological database, and the magnitude of the uncertainty factor used in the derivation of the reference dose.

For example, an HI of 2 will present a greater concern if the uncertainty factor (UF) used in calculating the RfD was 10 rather than 1,000. Similarly, an HI of 2 is of greater concern if the toxicity endpoint is very severe in nature (i.e. teratogenicity versus subtle enzyme changes). When an HI greatly exceeds unity, the risk assessor should consider the possibility of subchronic or acute health effects at the determined exposure level. Additionally, when the HI greatly exceeds unity, chronic health effects of greater severity than those manifested at the reference dose may be cause for concern and should be considered.

5.1.2 CARCINOGENIC RISK EVALUATION

The incremental lifetime cancer risk is the estimate most relevant to the evaluation of carcinogenic risk at Superfund sites. As used by EPA, it corresponds to the upper 95 percentile on the probability (when based on animal data) or to the maximum likelihood estimate (when based on human data) of developing cancer over a 70 year lifetime from possible exposure to hazardous substances attributed to a particular Superfund site. The incremental lifetime cancer risk estimate (commonly referred to as simply the cancer risk estimate) is computed as follows:

$$\text{Incremental Cancer Risk} = \text{Exposure Dose (mg/kg/day)} \times \text{Carcinogenic Potency (mg/kg/day)}^{-1}$$

The exposure dose (mg/kg/day) corresponds to the average daily dose over a 70 year lifetime. The carcinogenic potency estimate as derived by EPA corresponds to the upper 95 percentile of the confidence limit on the slope of the dose-response curve. In identifying cancer potency estimates for the evaluation of cancer risk , it is very important to select the most recent EPA cancer potency estimate relevant to the route of exposure being evaluated. The best resource for current potency estimates is the IRIS database.

5.1.2.1 Less-Than-Lifetime Exposure

As mentioned in section 5.1.1.2, actual and potential exposures at Superfund sites are often less-than-lifetime in duration. For carcinogenic effects, when an exposure is less-than-lifetime in duration, doses are still averaged over a 70-year lifetime. The following discussion presents several issues that the risk assessor may wish to discuss in the risk characterization section when exposures are known or assumed to be for a period of less than 70 years (a lifetime).

Presently animal studies used to derive dose-response values for carcinogenic effects (cancer potency factors) are based on lifetime or close to lifetime dosing experiments. This is to avoid or minimize the uncertainty associated with extrapolation from a less-than-lifetime to a lifetime daily dose. With humans, we often encounter exposures that are for a fraction of a lifetime and we must characterize risk given the tools available to us (cancer potency factors based on a lifetime of exposure). Convention has led risk assessors in this situation to merely average the human subchronic dose over a 70-year lifetime. When averaging a subchronic dose over 70 years and applying an EPA cancer potency factor, the risk assessor implicitly assumes that a large dose incurred over a short period of time is toxicologically equivalent to a smaller dose incurred over an entire lifetime. The risk assessor may wish to discuss the uncertainties involved in this assumption.

For example, humans may have efficient but saturable DNA repair systems, in which case, doses of short duration yet great in quantity may have higher associated cancer risk than the same total dose delivered on a daily basis over a lifetime. On the other hand, humans may have saturable uptake and/or metabolic systems. In such a case, a given total dose delivered over a shorter period of time may have less risk associated with it. In addition, the latency period for individual carcinogens may differ significantly.

Thus, it is not possible to state with certainty what effects the lifetime averaging approach will have on a less-than-lifetime carcinogenic risk assessment.

5.1.2.2 Extrapolation of Potency Factors Across Routes of Exposure

In some cases, potency factors are available for both ingestion and inhalation routes of exposure. For instance, EPA has established separate potency factors for trichloroethylene based on the oral and inhalation routes of administration. When route-specific cancer potency factors are available, the risk assessor should use the potency factor relevant to the route of exposure for estimating carcinogenic risk.

In other cases, EPA has derived either an oral potency factor or an inhalation potency factor but not both. In these situations, it may be appropriate to apply the available potency factor established for a particular route of exposure to a different exposure route of concern. The risk assessor however, must exercise extreme care because there are often route-specific toxic effects and the absorption, distribution, and metabolism of xenobiotics can vary significantly depending upon the route of administration. For instance, several heavy metals are known to be carcinogenic when inhaled as dusts or metal fumes. These metals (nickel, cadmium, and chromium VI) are not carcinogenic when ingested. The observed tumors resulting from exposure to these metals occur at the site of entry (the lung, in this example). Distant site tumors requiring systemic uptake and distribution of the contaminant are not observed. Thus, it would be inappropriate to use the EPA inhalation potency factor for assessing ingestion risks for these metals.

It may be appropriate to extrapolate a potency factor across routes of exposure when the compound has been found to be carcinogenic by both routes of exposure yet only one potency estimate is available. Even if a compound has not been shown to be carcinogenic by the route requiring assessment, it may still be appropriate to assess its carcinogenicity if there is reasonable justification for so doing. As an example, assume for a given compound that only an oral potency factor is available. There are not any studies demonstrating its carcinogenicity by the inhalation route, yet it is known that it is absorbed in experimental animals and humans when inhaled. In addition, the compound, which causes liver cancer when ingested, causes various forms of liver toxicity when inhaled by humans and test animals. To be adequately protective of public health, it may be appropriate to estimate the potential carcinogenic risks of the compound via inhalation using the ingestion potency factor.

The risk assessor should consider the relevance of the evidence of carcinogenicity by all routes of exposure before extrapolating potency factors. In particular, compounds that have not been shown to be carcinogenic by a particular route should be closely examined to determine if they have been adequately tested. In addition, relative absorption factors may need to be modified if there are route specific differences in the uptake of a compound. If first-pass metabolism by the liver or metabolism by pulmonary cells has important consequences with regard to the delivered tissue dose of the contaminant or toxic metabolite, it may be appropriate to modify the risk equation before applying the available potency factor. The use of any modifying factors that take into account differences in absorption, metabolism, etc. between routes of exposure must be fully explained in the risk assessment.

The dermal route of exposure is an important one for Superfund risk assessments. The carcinogenic risks posed by direct contact with contaminated soil or surface water must often be assessed at hazardous waste sites. Currently, EPA has not derived any cancer potency factors for the dermal route of exposure. In an attempt to address this shortcoming, the risk assessor should consider the use of potency factors derived from other routes of exposure. Generally, ingestion potency factors are used as surrogates for dermal potency factors. Implicit in this assumption is the fact that the potency of a given compound via the dermal route of exposure is equivalent to the compound's potency via the oral route of exposure. This approach should be followed with caution. The risk assessor should consider bioavailability, absorption, the effects of skin metabolism, the effects of first-pass hepatic metabolism, and other relevant data before applying ingestion potency factors to dermal exposure situations.

5.2 OBSTACLES TO THE EVALUATION OF RISK

In some instances, there may be obstacles to the evaluation of risk. Some of these have already been discussed in the exposure assessment section of the guidance. It was felt that other limitations warranted special attention and thus the lack of suitable dose-response criteria and compounds not selected as contaminants of concern are addressed in the following sections.

5.2.1 COMPOUNDS LACKING SUITABLE DOSE-RESPONSE CRITERIA

For many chemical compounds detected at hazardous waste sites, dose-response data may not be available. It is EPA policy that the presence or absence of appropriate dose-response data is not a criterion for selecting contaminants of concern at Superfund sites. When dose-response information is not available for a particular compound, it may be appropriate to use a dose-response value from another compound with similar chemical structure to aid in the selection of contaminants of concern and in the evaluation of risk.

For example, a risk assessor may find it appropriate to select a contaminant without dose-response data, such as 3,3'-dichlorobenzidine, as a contaminant of concern if it is present at high levels and/or at high frequency in one or more media. Furthermore, because of its structural similarity to the potent human carcinogen benzidine, 3,3'-dichlorobenzidine may be carcinogenic to humans. Due to the structural similarity, it may be appropriate to apply the cancer potency factor for benzidine to 3,3'-dichloro-benzidine. Such structure-activity arguments may be appropriately used in the contaminant of concern selection process, as discussed in Section 2.2. When possible, toxicological information on the specific chemical should be obtained. Such information may exist even if EPA approved standards or criteria have not yet been derived.

In the absence of well studied structural analogues, EPA may allow the risk assessor to derive a dose-response value gleaned from laboratory toxicology studies. EPA toxicologists must be consulted at the earliest possible time regarding the choice of the studies and the specific methodology. Derivation of dose-response values must be well documented and may only be appropriate for sites at which a major contaminant lacks an EPA derived dose-response value.

Whenever a surrogate dose-response value based on structure-activity considerations or a newly derived value is used, the risk assessor must fully document the basis for the approach in the risk characterization section of the risk assessment. The text must convey the scientific uncertainties associated with the quantitative risk estimate calculated for the specific contaminant. The discussion should include an analysis of the likely toxic endpoint, the magnitude and severity of potential health effects, and the evidence that the contaminant causes the effects in humans. The impact of the risk posed by the single contaminant to the total risk estimate also must be fully explained, because the confidence in the risk estimates for the other contaminants at the site may be much higher.

Lastly, when a cancer potency estimate, reference dose, or other suitable criterion is not available for a contaminant of concern or a structural analogue and derivation of a dose-response value is not a possibility, the risk assessor is faced with an important decision. It may be appropriate to exclude these chemicals from the quantitative risk assessment and instead discuss the risk to public health qualitatively in the risk characterization section. This approach will be well suited to sites having several other hazardous contaminants present which are qualitatively assessed.

5.2.2 COMPOUNDS NOT QUANTITATIVELY EVALUATED

Most Superfund sites contain complex mixtures of chemicals, many of which are not included in the quantitative risk assessment process. Two categories of chemical contaminants not included in the risk assessment calculations are: chemicals that are known to be present based on the results of the analytical sampling, but which were not selected as contaminants of concern; and chemicals suspected of being present but which were not part of the laboratory analysis. In both cases, the risk assessor must discuss in the risk characterization how the presence of such chemicals affects the numerical risk estimates generated by the quantitative assessment.

Of the chemicals that are quantitatively detected in samples taken at a site, only a subset (contaminants of concern) are chosen for quantitative risk assessment based on frequency, toxicity, concentration, etc. If many chemicals are not selected as contaminants of concern and are present at high concentrations, high frequency, or exhibit toxic potential, the risk assessor must qualitatively assess the risk posed by them. Comparisons can be made between these chemicals and others that were quantitatively assessed. Any available information on the ability of these chemicals to modulate the toxicity of other chemicals found at the site should also be discussed.

In some cases, important contaminants may have been chosen as contaminants of concern for a site, but suitable dose-response values were not available for risk quantitation. For instance, a waste site may contain many probable or possible human carcinogens that could be contaminants of concern, but the compounds do not have cancer potency factors. Hydrazine, 1,1,2,2-tetrachloroethane, 1,4-dioxane, diaminotoluene, formaldehyde, and urethane are all Group B2 carcinogens lacking an EPA approved cancer potency factor. Styrene and methylphenols are possible human carcinogens (Group C) which also lack EPA cancer potency factors. When contaminants of concern are not quantitatively assessed in the risk characterization, the risk assessor should point out the possibility of actually under-estimating risk.

Other chemicals that may not enter the quantitative risk assessment include chemicals that may be known or suspected to be present, but which were not analytes of the sampling program. For instance, many sites are known to be contaminated by coal tar wastes. Numerous sophisticated analyses have revealed that coal tar is an extremely complex mixture of hundreds of PAHs and related compounds, such as nitrogen and sulfur analogues. As part of routine Superfund analyses, however, only 16 PAH compounds are reported. In situations such as this, the risk assessor should discuss that the quantitative risk assessment focused only on a subset of all the compounds suspected of being present.

At other sites, the laboratory results may indicate that there were numerous unidentified peaks in the chromatograms or numerous "tentatively identified compounds." Often total organic carbon analyses can demonstrate that the detected and identified compounds account for only a small fraction of the total contaminants present. This outcome is due to the fact that routine analyses are targeted to a specific set of hazardous substances. When such information is available, the risk assessor should discuss its significance in the risk characterization section.

Often the toxicity of a contaminant will depend on the specific form or species present. When the species is unknown, it may be appropriate for the risk assessor to assume that the most toxic form is present at the site. If there is a reasonable basis to conclude that this assumption is not correct, the risk assessor should discuss it fully. For instance, data from a site may only indicate the total cyanide concentration. If the risk assessor has reason to believe that the cyanide is present as the less toxic ferric cyanide based on knowledge of waste practices or manufacturing processes, then this fact should be discussed. Similarly, if the nickel is known to be soluble nickel chloride waste material from a particular process instead of the more toxic nickel sulfides, the risk assessor should discuss its significance to the assessment of inhalation risks to airborne soil from the site.

5.3 RISK SUMMARY

The summary of site risks is perhaps the most important aspect of the risk assessment. It represents the assimilation of the exposure and the toxicity assessment in such a manner that is useful for decision making. Often the risk estimates generated in this section serve as the basis for remedial actions. After calculating a risk, the risk assessor should include an interpretation of the risk levels in terms of their significance, pointing out the strengths and weaknesses of the risk assessment.

5.3.1 RISK PRESENTATION

The risk summary section of the risk assessment should include a summary of the risk estimated for each exposure pathway. The risk estimates are most effectively conveyed in table form for each media and exposure pathway listing the risk attributed to each contaminant of concern. Present risk estimates should be distinguished from future potential risk estimates. Similarly, carcinogenic and noncarcinogenic risks should also be differentiated and presented in separate tables. It is also EPA policy to assume additivity of carcinogenic risk thus the total carcinogenic risk estimate for each exposure pathway should be included in every analysis. Likewise, the Hazard Index should be summed for those compounds exhibiting similar toxic endpoints.

Since risk estimates are closely related to exposure and potency, it is beneficial to highlight some of the exposure and potency information in the risk summary tables. The suggested format for the summary tables for carcinogenic and noncarcinogenic health risks are presented in Tables 5-1a and 5-1b, respectively. Often there is a tendency to make the summary tables complex in an attempt to convey a large amount of data. However one should strive to make the tables as clear and easy to read as possible. Only one significant fugure should be presented for the resulting carcinogenic risk estimate and at most two significant figures for the Hazard Index.

TABLE 5-1a

EXAMPLE TABLE FOR SUMMARIZING LIFETIME CANCER RISK

SUMMARY OF EXCESS LIFETIME CANCER RISK POSED BY THE PRESENT INGESTION OF DRINKING WATER (1)

			CONCENTRATION		EXPOSURE DOSE		LIFETIME CANCER RISK	
CARCINOGENIC CONTAMINANTS OF CONCERN	CANCER WEIGHT OF EVIDENCE	CANCER POTENCY FACTOR (mg/kg/day) -1	AVERAGE (mg/l)	MAXIMUM (mg/l)	AVERAGE CASE (mg/kg/day)	REASONABLE WORST CASE (2) (mg/kg/day)	AVERAGE CASE	REASONABLE WORST CASE (2)
Compound A	B2	2.5 x 10-5	9	85	3.5	7.0	9 x 10-5	2 x 10-4
Compound B	A	7.7 x 10-6	2	66	5.0	23.0	4 x 10-5	2 x 10-4
						TOTAL	1 x 10-4	4 x 10-4

(1) The risk posed by each present and future potential exposure pathway should be summarized separately

(2) Reasonable worst-case exposure and risk estimates should be flagged with a footnot alerting the reader to the fact that it was based on the maximum concentration detected relevant to the exposure and medium of concern

TABLE 5-1b

EXAMPLE TABLE FOR SUMMARIZING LIFETIME CANCER RISK

SUMMARY OF NONCARCINOGENIC RISKS POSED BY THE PRESENT INGESTION OF DRINKING WATER (1)

		CONCENTRATION		EXPOSURE DOSE		HAZARD INDEX		
NONCARCINOGENIC CONTAMINANTS OF CONCERN	RfD (OR OTHER STD) (mg/kg/day)	AVERAGE (mg/l)	MAXIMUM (mg/l)	AVERAGE CASE (mg/kg/day)	REASONABLE WORST CASE (2) (mg/kg/day)	AVERAGE CASE	REASONABLE WORST CASE(2)	ENDPOINT OF CONCERN
Compound A	12	9.0	85.0	3	6	0.3	0.5	liver
Compound B	10	0.6	15.0	7	19	0.7	1.9	blood
Compound C	8	0.3	80.0	6	24	0.8	3.0	liver
		Total HI for compounds with similar endpoints (A + C) =				1.1	3.5	liver
		Total HI for compounds with similar endpoints (B) =				0.7	1.9	blood

---

(1) The risk posed by each present and future potential exposure pathway should be summarized separately.

(2) Reasonable worst-case exposure and risk estimates should be flagged with a footnot alerting the reader to the fact that it was based on the maximum concentration detected relevant to the exposure and medium of concern.

5.3.2 EVALUATING RISKS POSED BY MORE THAN ONE EXPOSURE PATHWAY

As mentioned above, risks are presented separately for each exposure pathway. Sometimes it is asked whether risks should be summed across exposure pathways to approximate a total site risk. Since it is a simple matter of arithmetic that is done after the presentation of risk by exposure pathway, this final step does not significantly alter the risk assessment. A decision to add risks across exposure pathways should reflect the intended use of the finished report and the relevance of multiple exposure pathways.

It may be desirable to compute the risk to a given receptor corresponding to a particular exposure scenario. This may involve the addition of risk from different exposure pathways (ingestion, inhalation, dermal contact), across different media (water, air, and soils), as well as across different exposure locations (on-site, off-site). Because there may be numerous relevant exposure scenarios, a certain degree of subjectivity is involved in selecting the appropriate exposure pathways, media, and exposure locations to include. Once again, the selection of relevant exposure pathways, media, and exposure locations should reflect the project goals. In adding risks across pathways, media, and exposure locations, care should be taken to ensure that the risks are for a given receptor and that there is not a double counting of risk (i.e. in terms of frequency or duration).

While these options have been discussed, it is not mandatory that total site risk or risk posed by several exposure pathways be summed. This is because one of the uses of the risk estimate is to identify environmental media in need of remediation. With a risk assessment broken down into exposure pathways (essentially media), decisions can be made as to which exposure pathway(s) warrant remediation and the priority to assign to each.

5.3.3 RISK INTERPRETATION

Because a lot of scientific notation can be very distressing to the unaccustomed reader, it is suggested that a brief interpretation of the risk estimates be performed. This discussion should touch on the significance of the risk under evaluation and how it could impact the selection of remedial actions. At present, EPA has not defined what constitutes a significant or insignificant level of risk. The Agency has however, made it known what constitutes the overall risk based clean up goal for Superfund sites, namely anything that falls between a 10^{-4} to 10^{-7} excess cancer risk level. On the subject of non-carcinogenic compounds, the Agency has been a bit quieter. In the absence of an Agency decision on acceptable HI values, it is the approach of the Region 1 Office that HI values < 1 are acceptable and HI values > 10 are of concern such that they are likely to warrant remediation. HI values between 1 and 10 should be evaluated per Section 5.1.1.3.

In describing risk, it is often advantageous to highlight the information from the risk summary tables emphasizing which exposure pathways were determined to be significant and which were relatively insignificant. Similarly, identification of a few selected compounds of concern having a major impact on the risk estimate can also be very beneficial for the reader. No risk assessment however is complete without a discussion of the uncertainty and limitations of the findings which have been described throughout the guidance document and which are briefly highlighted in the following section.

6.0 UNCERTAINTY AND LIMITATIONS OF THE RISK ASSESSMENT

The final section of the risk assessment should address uncertainties and limitations in the analysis. This section should clearly state the major limitations, sources of uncertainty and, if possible, provide an indication as to whether they have resulted in over- or under-estimations of risk. Examples of uncertainties and limitations that should be addressed include:

- Particulars of sample data that may tend to bias results
  - adverse weather conditions.
  - reliance on historical data.
  - restrictions on amount or types of samples collected.
  - intentional bias in sample collection or analysis.
  - heterogeneity of sample data.
- The methodology used to compile and analyze the data for use in the risk assessment.
  - detection limits not documented by laboratories.
  - selection of data to generate site statistics (mean and maximum concentrations, detection frequencies).
  - uncertainty in sample analysis.
- Reliance upon models that have not been verified or used extensively to predict contaminant concentrations or exposure doses.
- The dose-response assessment
  - limitations of the study used to derive the cancer potency factor or reference dose for a major contaminant in the risk assessment.
  - weight of evidence for carcinogens/uncertainty factor in reference dose.
  - use of structure activity information.
  - extrapolation of potency estimates across routes of exposure.
  - uncertainties arising from the application of potency estimates to mixtures when the toxicity of individual constituents is unknown.

- The exposure assessment
  - exposure parameters may be based on limited controlled laboratory studies or else merely a "best guess".
  - inability to predict all variations in human behavior.
  - lack of or uncertainy in the data used to derive relative absorption factors.
- The risk characterization
  - uncertainty in the dose-response estimate leads EPA to quantify the upper 95% confidence level on risk. Thus the true risk is likely to be lower than the quantified risk estimates but no one knows exactly just how much lower.
  - by definition, risk is a function of both exposure dose and toxicity. Thus if either or both exposure dose or toxicity are not accurate, the risk estimate will be a poor indication of risk.
  - risk posed by contaminants not selected for quantitative assessment.

Depending upon the time and budget available for the risk assessment, a sensitivity analysis could be conducted to determine which parameters have the greatest influence on the resulting risk estimates.

7.0 REFERENCES

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EPA 1986, Superfund Public Health Evaluation Manual, Office of Emergency and Remedial Response, Office of Solid Waste an Emergency Response, Washington D.C., October 1986, EPA 540/1-86/060.

Section 3.0 Dose-Response Assessment

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8.0 GLOSSARY

Absorption: The uptake of water or dissolved chemicals by a cell or an organism.

Absorption Factor: The fraction of a chemical making contact with an organism that is absorbed by the organism.

Acceptable Daily Intake (ADI): A term formerly used to refer to an estimated exposure level that would not result in adverse health effects.

Acceptable Intake Chronic (AIC): The highest human intake of a chemical, expressed as mg/kg/day, that is not expected to cause adverse effects when exposure is long-term (lifetime).

Acceptable Intake Subchronic (AIS): The highest human intake of a chemical, expressed as mg/kg/day, that is not expected to cause adverse effects when exposure is short term (but not acute).

Acute: Occurring over a short period of time; used to describe brief exposures and effects which appear promptly after exposure.

Agency for Toxic Substances and Disease Registry (ATSDR): Agency which has primary responsibility for health assessments at Superfund sites.

Ambient Water Quality Criteria (AWQC): The health based water quality criterion is an estimate of the ambient surface water concentration that shall not result in adverse effects in humans.

Applicable or Relevant and Appropriate Requirements (ARARs): Applicable requirements are cleanup standards, standards of control, and other environmental protection requirements promulgated by law that address contaminants at Superfund sites. Relevant and appropriate requirements are cleanup standards, standards of control, and other protection requirements while not applicable to hazardous substance, contaminant, remedial action, location, or other circumstances at CERCLA sites, address problems or situations sufficiently similar to those encountered at the Superfund site such that their use is well suited to the particular site.

Cancer: A general term frequently used to indicate any of various types of malignant neoplasms, most of which invade surrounding tissues, may metastasize to several sites, and are likely to recur after attempted removal and to cause death of the patient unless adequately treated.

Cancer Potency Factor: The upper 95% confidence limit (when based on animal data) or the maximum likelihood estimate (when based on human data) on the slope of the dose-response curve expressed in units of $(mg/kg/day)^{-1}$.

Carcinogen: An agent or substance capable of inducing a tumor. Includes both those substances that produce benign tumors as well as malignant tumors.

Chronic: Occurring over a long period of time; used to describe ongoing exposures and effects that usually develop only after long exposure periods.

Contaminants of Concern: Refers to the subset of contaminants identified at a Superfund site, that are selected for risk characterization based on their toxicity, concentration, frequency of detection, persistence and mobility.

Dose: The quantity of a chemical to which an organism is exposed.

Drinking Water Equivalent Level (DWEL): Established by EPA's Office of Drinking Water to protect against adverse health effects resulting from a lifetime of exposure to noncarcinogenic contaminants in drinking water.

Environmental Transport Medium: Mode of moving contaminant (air groundwater, etc).

Epidemiological Studies: Investigation of elements contributing to disease or toxic effects in human populations.

Exposure: Contact with a chemical or physical agent.

Exposure Pathway: An exposure pathway consists of four elements: (1) a source and mechanism of chemical release to the environment, (2) an environmental transport medium, (3) a point of potential human contact with the contaminated medium, (4) a human exposure route at the contact point.

Hazard Index (HI): The term used to describe the potential for noncarcinogenic health effects. It is computed by dividing the exposure dose by the reference dose or other suitable noncarcinogenic standard or criteria for an individual chemical.

Health Effects Assessments: A group of reports prepared by EPA which present a brief summary and evaluation of information relevant to a preliminary interim assessment of the adverse health effects of various chemicals.

Hematopoietic System: The system responsible for producing and maintaining the constituents of blood. Includes the circulating blood, lymphoid tissue, and the bone marrow.

Hepatic: Associated with supplying or draining the liver.

Histopathology: A branch of pathology concerned with the tissue changes characteristic of disease.

Indicator Compounds: See contaminants of concern.

Integrated Risk Information System (IRIS): Computer database which provides updated dose-response information for many chemicals. Represents the principal resource for current EPA dose-response information.

International Agency for Research on Cancer (IARC): Non-regulatory agency involved in cancer research and which developed an approach to classifying the cancer weight evidence based on human and animal data.

Lifetime Health Advisory (HA): Guidelines established by the EPA Office of Drinking Water to protect against noncarcinogenic health effects of compounds in drinking water. Derived strictly based on health considerations.

Lowest Observable Adverse Effect Level (LOAEL): The lowest dose in an experiment which produced an observable adverse effect.

Maximum Contaminant Levels (MCL): Enforceable chemical specific standards set under the Safe Drinking Water Act for public water supplies. MCLs are based on health, treatability, and cost considerations.

Maximum Contaminant Level Goal (MCLG): Non-enforceable chemical specific drinking water concentrations established under the Safe Drinking Water Act that are entirely health based.

Metabolism: The sum of the chemical reactions occurring within a cell or a whole organism; includes the energy-releasing breakdown of molecules (catabolism) and the synthesis of new molecules (anabolism).

Metabolite: Any product of metabolism, especially a transformed chemical.

Mutagenicity: The capacity of a chemical or physical agent to cause permanent alteration of the genetic material within living cells.

No Observable Adverse Effect Level (NOAEL): The highest dose in an experiment which did not produce an observable adverse effect.

Non-detect (ND): The term used to refer to a chemical that is not present in sufficient quantity to be accurately quantified.

Pica: An abnormal desire to eat substances not normally eaten.

Receptor: An organism that receives, may receive, or has received environmental exposure to a chemical.

Reference Dose (RfD): The RfD is based on EPA's identification of the threshold effects level with an added margin of safety. The RfD represents an estimate of the daily dose level (mg/kg/day) for a particular compound that is likely to be without appreciable risk of deleterious effects when exposure occurs over a given period (usually a lifetime).

Relative Absorption Factor: The ratio of the estimated absorption factor for the site specific medium and route of exposure to the known or estimated adsorption factor for the laboratory study from which the cancer potency factor or reference dose was derived.

Risk: The potential for realization of unwanted negative consequences or events.

Suggested No Adverse Response Level (SNARL): A term formerly used by EPA and the National Academy of Sciences corresponding to a contaminant level in drinking water at which adverse health effects would not be anticipated.

Superfund Public Health Evaluation Database (PHRED): Computer database available through EPA with chemical, physical, and toxicity information on various compounds.

Teratogenicity: The capacity of a physical or chemical agent to cause non-hereditary congenital malformations (birth defects) in offspring.

Toxic/Target-Endpoint: The most sensitive yet significant noncarcinogenic effect caused by the administration of a compound. Examples include enzyme, weight, gross morphological, and functional changes. Also the target endpoint serves as the basis from which some of the noncarcinogenic criteria (RfDs) are derived.

Toxicity: The quality or degree of being poisonous or harmful to plant, animal or human life.

Uncertainty Factor (U.F.): A factor used to account for the interspecies and intraspecies differences, severity of adverse effects, and the adequacy of data when determining the reference dose.

Xenobiotic: A chemical compound that is foreign to a living organism.

PART 2

GUIDANCE FOR
ECOLOGICAL RISK ASSESSMENTS

DRAFT FINAL

JUNE 1989

U.S. ENVIRONMENTAL PROTECTION AGENCY
REGION 1

PART 2

GUIDANCE FOR ECOLOGICAL RISK ASSESSMENTS

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1.0 INTRODUCTION

The Superfund Amendments and Reauthorization Act (SARA) of 1986 emphasize the necessity to assess the actual and potential risks to public health and the environment at each NPL site (SARA 110 and CERCLA 104(i)). Ecological Risk Assessments have become an integral part of the RI/FS process, and have provided important information in the evaluation of remedial alternatives at hazardous waste sites. Because many terms have been used to describe what we are calling an ecological risk assessment, we have provided the following definitions.

> Environmental Impact Assessment can be defined as the following:
>
> A broad field that includes all activities that attempt to analyze and evaluate the effects of human action on natural and anthropogenic environments (after Suter et al. 1987).
>
> Ecological Impact Assessment, a subcategory of environmental impact assessment, addresses impacts to non-human receptors:
>
> A procedure that documents or estimates the potential for occurrence of impacts within an ecosystem or any part of an ecosystem.
>
> Ecological Risk Assessment is the subcategory of ecological impact assessment that estimates impacts:
>
> A procedure that estimates the possibility of adverse effects occurring in an ecosystem or any part of any ecosystem as a result of a perturbation.
>
> Ecological Injury Assessment measures adverse effects that have already occurred, and can provide valuable input into ecological risk assessment:
>
> A procedure that quantitatively measures adverse effects that have occurred in an ecosystem or any part of an ecosystem.

The types of data required to assess ecological risk frequently differ from those required for public health risk assessments or other types of assessments that occur at hazardous waste sites (e.g., waste characterization). The purpose of this document is to provide ideas and guidance to project managers and other hazardous waste personnel (1) when planning sampling strategies to support ecological risk assessments and (2) when using data to assess the probability of adverse ecological effects occurring as a result of chemical release from a site. Although we have emphasized the collection and use of data for ecological risk assessments, ecological data can also be very useful in other parts of the RI/FS process, such as in determining the extent of contamination and in evaluating the efficacy of remedial alternatives.

This document is largely the outcome of discussions held by the Region I work group on ecological risk assessment. It is intended to provide an overview of the process of evaluating ecological risks in the context of the Superfund program, and also to provide possible approaches to collecting the data needed to support the ecological assessment process[1]. Although the quantitative methods used to assess ecological risk have been most widely applied to aquatic systems, an attempt was made to include approaches for assessing risk to terrestrial systems as well.

The Region I work group recognized that a wide variety of approaches to ecological risk assessments were available. Possible approaches range from screening level assessments using available criteria (e.g., EPA water quality criteria) and available site data, to the use of complex models supported by extensive field sampling. The choice of the type and the level of detail for an ecological assessment conducted at Superfund sites depends on the following factors:

- Site-specific objectives, including level of precision (e.g., desired level of precision in field measurements or risk estimates). Such objectives might include:
  - -Determination of the extent or likelihood of impact
  - -Interim mitigation strategies
  - -Development of remedies
  - -Remediation criteria
- Quality and quantity of available site data
- Areal extent of contamination
- Degree of contamination (number, kinds, and concentrations of chemicals)

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[1] The Superfund Environmental Evaluation Manual, available in draft form as of this writing, provides additional discussion and background on Ecological Assessments in Superfund.

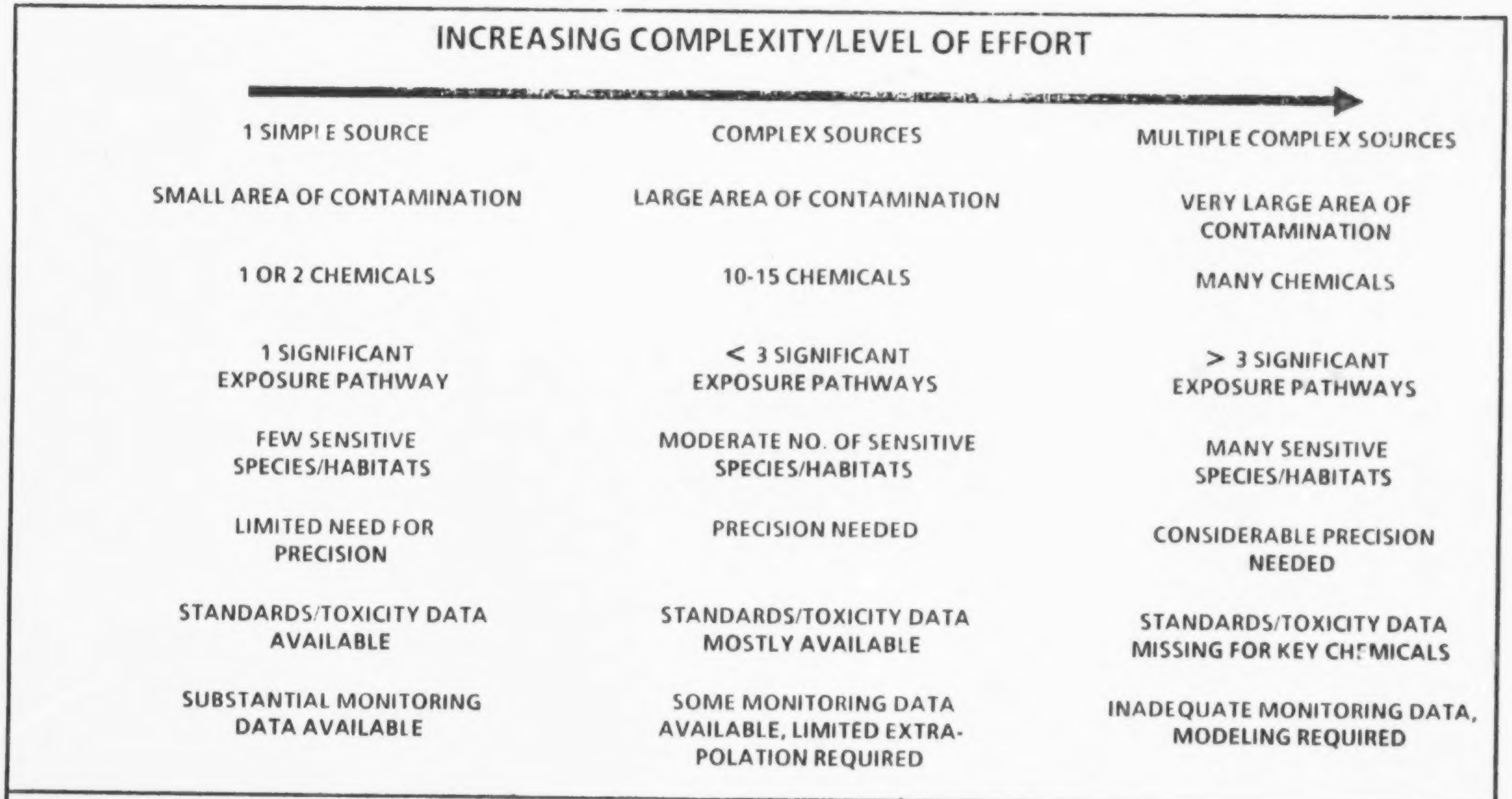
- Variation (temporally and spatially) in contamination
- Availability of standards/criteria and toxicity data
- Number and complexity of potential exposure pathways
- Characteristics of natural resources at risk
- Funding and time constraints on collection of additional data.

Figure 1, which is adapted from the Superfund Public Health Evaluation Manual (U.S.EPA 1986), illustrates the factors that can influence the complexity and corresponding level of effort needed for an ecological risk assessment. For example, the size of the contaminated area and its significance to the ecosystem is an important factor. Also, the numbers of different species and habitats of concern should be considered when deciding on an assessment approach. The relative data requirements and complexity of comprehensive models and field assessments depend on the biological endpoints selected, available field measurement techniques, and the degree of precision and realism desired in a model.

The remainder of this document is divided into three major sections. Section 2 addresses the collection of site-specific data needed to support ecological risk assessments. Section 3 describes a framework for conducting ecological risk assessments at Superfund sites, and emphasizes the integration of information from laboratory tests, field assessments, and models in assessing risk. Finally, Section 4 provides several specific approaches for assessing risk to systems exposed to chemical contamination in different media. This document cannot be definitive because the practice of assessing ecological risks is constantly evolving. For this reason, it is extremely important to solicit the involvement of ecologists and biologists at all stages of the process. The Region I Superfund Environmental Assessment Team is a valuable source of professionals with ecological expertise, and should be consulted at the earliest possible stage of the assessment. Other ecological professionals that may be consulted include the staff of EPA's Environmental Services Division, State Fish and Wildlife personnel, and the NOAA Coastal Resource Coordinator.

2.0 DATA COLLECTION TO SUPPORT ECOLOGICAL RISK ASSESSMENTS

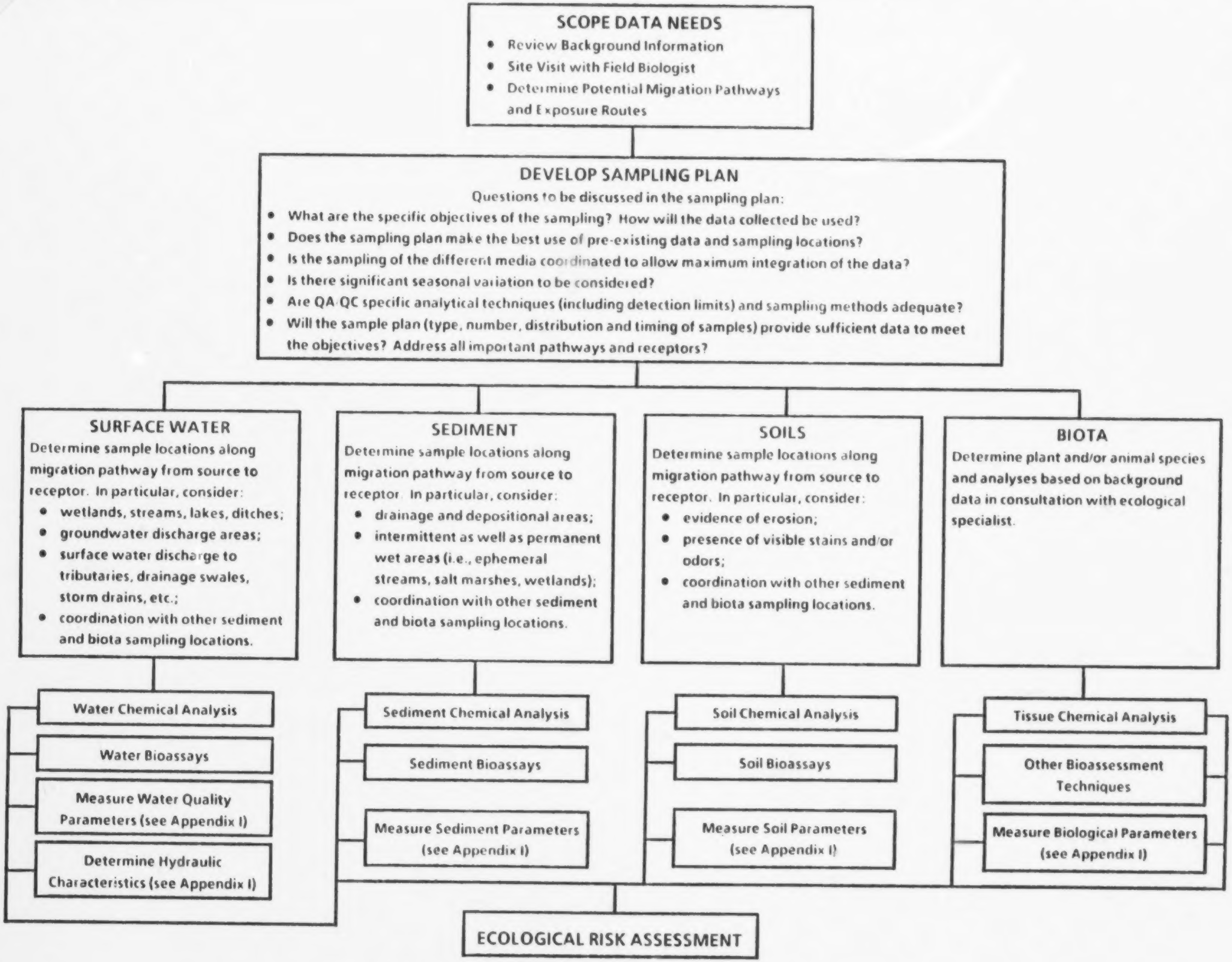
Figure 2 is a flow diagram that outlines an approach to determining sampling needs for ecological risk assessments at hazardous waste sites. The first step in Figure 2 is the collection of all available background information and a site visit by a qualified field biologist. An overall sampling plan is then developed to



INCREASING COMPLEXITY/LEVEL OF EFFORT

1 SIMPLE SOURCE	COMPLEX SOURCES	MULTIPLE COMPLEX SOURCES
SMALL AREA OF CONTAMINATION	LARGE AREA OF CONTAMINATION	VERY LARGE AREA OF CONTAMINATION
1 OR 2 CHEMICALS	10-15 CHEMICALS	MANY CHEMICALS
1 SIGNIFICANT EXPOSURE PATHWAY	< 3 SIGNIFICANT EXPOSURE PATHWAYS	> 3 SIGNIFICANT EXPOSURE PATHWAYS
FEW SENSITIVE SPECIES/HABITATS	MODERATE NO. OF SENSITIVE SPECIES/HABITATS	MANY SENSITIVE SPECIES/HABITATS
LIMITED NEED FOR PRECISION	PRECISION NEEDED	CONSIDERABLE PRECISION NEEDED
STANDARDS/TOXICITY DATA AVAILABLE	STANDARDS/TOXICITY DATA MOSTLY AVAILABLE	STANDARDS/TOXICITY DATA MISSING FOR KEY CHEMICALS
SUBSTANTIAL MONITORING DATA AVAILABLE	SOME MONITORING DATA AVAILABLE, LIMITED EXTRAPOLATION REQUIRED	INADEQUATE MONITORING DATA, MODELING REQUIRED

FIGURE 1. CONTINUUM OF ANALYTICAL COMPLEXITY FOR ECOLOGICAL RISK ASSESSMENT


SCOPE DATA NEEDS
- Review Background Information
- Site Visit with Field Biologist
- Determine Potential Migration Pathways and Exposure Routes

DEVELOP SAMPLING PLAN

Questions to be discussed in the sampling plan:
- What are the specific objectives of the sampling? How will the data collected be used?
- Does the sampling plan make the best use of pre-existing data and sampling locations?
- Is the sampling of the different media coordinated to allow maximum integration of the data?
- Is there significant seasonal variation to be considered?
- Are QA/QC specific analytical techniques (including detection limits) and sampling methods adequate?
- Will the sample plan (type, number, distribution and timing of samples) provide sufficient data to meet the objectives? Address all important pathways and receptors?

SURFACE WATER

Determine sample locations along migration pathway from source to receptor. In particular, consider:
- wetlands, streams, lakes, ditches;
- groundwater discharge areas;
- surface water discharge to tributaries, drainage swales, storm drains, etc.;
- coordination with other sediment and biota sampling locations.

SEDIMENT

Determine sample locations along migration pathway from source to receptor. In particular, consider:
- drainage and depositional areas;
- intermittent as well as permanent wet areas (i.e., ephemeral streams, salt marshes, wetlands);
- coordination with other sediment and biota sampling locations.

SOILS

Determine sample locations along migration pathway from source to receptor. In particular, consider:
- evidence of erosion;
- presence of visible stains and/or odors;
- coordination with other sediment and biota sampling locations.

BIOTA

Determine plant and/or animal species and analyses based on background data in consultation with ecological specialist.

Water Chemical Analysis
Water Bioassays
Measure Water Quality Parameters (see Appendix I)
Determine Hydraulic Characteristics (see Appendix I)
Sediment Chemical Analysis
Sediment Bioassays
Measure Sediment Parameters (see Appendix I)
Soil Chemical Analysis
Soil Bioassays
Measure Soil Parameters (see Appendix I)
Tissue Chemical Analysis
Other Bioassessment Techniques
Measure Biological Parameters (see Appendix I)
ECOLOGICAL RISK ASSESSMENT

FIGURE 2. FLOW CHART FOR ENVIRONMENTAL SAMPLING

characterize the following: the extent of contamination; the fate and transport of contaminants; receptor organisms and habitats; and potential exposure pathways. Sample locations are selected within each media based upon the identified potential for exposure to biota.

As can be seen in Figure 2, the following six questions are central to the successful design of any sampling plan:

(1) What are the specific objectives of the sampling effort? How will the data collected be used?

(2) Does the sampling plan make the best use of pre-existing data and sampling locations?

(3) Is the sampling of the different media coordinated to allow maximum integration of the data?

(4) Is there significant seasonal variation to be considered?

(5) Are QA/QC, specific analytical techniques (including detection limits) and sampling methods adequate?

(6) Will the sampling plan (type, number, distribution and timing of samples) provide sufficient data to meet the objectives? Does the sampling plan address all the important pathways and receptors?

The bottom part of Figure 2 lists general sampling needs that should be considered for each media. It should be noted that all of these data are not necessary for every assessment. If only a screening level assessment is envisioned for a site, then less effort and resources should be spent collecting data. It is important in any sampling effort, however, that sampling for all media be integrated into a single coordinated plan. For example, benthic and sediment samples should be taken at the same locations for bioaccumulation studies.

The types of data collected at sites can be grouped into three general categories; chemical data, bioassessment techniques, and physical parameters. When used together and enhanced using models, a combination of these techniques form the most effective strategy to characterize the potential for adverse ecological effects. However, the relative reliance on chemical analyses, bioassays, or modeling may differ depending on the contamination present at the site, the medium being assessed, and the objectives of the assessment.

Chemical analyses are routinely performed at most sites. Analytical techniques for water and sediment/soil media are well established and can be found through the EPA Contract Lab Program (CLP). One of the more frequent problems in using chemical data for ecological risk assessment is that the detection limit for a given chemical may be greater than its Ambient Water Quality Criteria or toxicity value. For example, the Ambient Water Quality Criteria for mercury is 0.025 ug/l while the typical CLP detection limit is 0.2 ug/l. Therefore a lab result of nondetect (ND) does not mean that the contaminant is present below a toxic level.

Bioassays are a group of tests that involve the exposure of organisms to test media (e.g. water, sediment, soil, or sediment/soil extracts) under controlled conditions to determine whether the exposure results in adverse effects. Bioassays may be performed in the laboratory or with caged organisms in the field. Many organisms, from mammals to bacteria and cultures of cells, have been used in such testing. These tests use a variety of endpoints (responses) to determine biological effects of toxic substances, the most common endpoint being death of the organisms. Other endpoints frequently used include developmental abnormalities, behavioral changes, changes in reproductive success and other physiological effects such as alteration of growth and respiration.

As will be discussed in Section 3, bioassays are particularly useful in estimating the toxicity of biologically active compounds present at waste sites that are not measured or detected in standard chemical analyses. More information on specific bioassessment techniques can be found in USEPA (1989), USEPA (1987), Christopherson et al. (1987), and Greene et al. (1988), USEPA (1987). A Superfund Bioassessment Manual is also in preparation and is expected to be available by the end of the 1989 calendar year.

An important supplement to chemical and bioassay data is the collection of data to characterize the physical and chemical characteristics of each medium that may influence exposure or toxicity. These parameters will maximize the utility of the chemistry and bioassay data and include:

- water quality characteristics (e.g., hardness),
- hydraulic characteristics (e.g., flow rates),
- sediment and soil characteristics (e.g., organic carbon content) and
- characteristics of collected biota (e.g., lipid content).

Appendix 1 provides descriptions of specific media characteristics and brief rationales for their use. Only some of these characteristics are likely to be needed for any one site assessment. For this reason, it is important that the people who will be using the data (e.g., risk assessors) be consulted during the work plan stage to determine which of the parameters will be most useful and thus necessary to obtain.

3.0 THE ECOLOGICAL RISK ASSESSMENT PROCESS

A flow diagram of the ecological risk assessment process is shown in Figure 3. As can be seen, the assessment is refined during each new step as more data are collected and used.

As can be seen in Figure 3, once available information has been reviewed and the site has been visited, the first step usually undertaken is to identify potentially contaminated media, the species and habitats that are potentially affected, and the chemicals of potential concern. The characterization of the biological receptors can be based on a review of available data such as maps of endangered or threatened species habitats, interviews with knowledgeable people (e.g., State Fish and Wildlife personnel), and a field survey. In addition, a qualitative evaluation of potential effects and the likely fate of the contaminants of concern can be useful for focussing the assessment. Contaminant concentrations at the site may also be evaluated relative to background or reference-area conditions. Subsequent steps in a risk assessment should only be performed for contaminants that substantially exceed background concentrations.

The next step shown in Figure 3 is to conduct a screening level risk assessment for the biological receptors, contaminated media, and chemicals of potential concern that have been identified. In general, a screening level risk assessment is a simple ecological risk assessment that uses available or easily obtainable data and is often based on established criteria and worst case assumptions concerning exposure. For terrestrial receptors, there are not any criteria analogous to the Ambient Water Quality Criteria, hence the decision to conduct a more detailed study is often qualitative and based on professional judgement (which tends to be harder to document or duplicate). Some screening level risk assessments, particularly for aquatic systems, are based on simple, inexpensive field bioassays such as those using Microtox or an amphipod. Simple bioassays are not yet widely used for screening level risk assessments for terrestrial systems. However, toxicity tests using seed germination, root elongation, and worm mortality are available and could easily be applied to this purpose.

Based on the results of the screening level risk assessment, a more detailed assessment may be conducted. Table 3-1 contains an outline to assist the risk assessor in conducting a more thorough ecolgocial risk assessment. It should be noted that the steps identified in Table 3-1 are often conducted in an iterative manner as the assessment proceeds. In detailed assessments, chemical analyses of media, bioassessment techniques, and models are often used in conjunction with laboratory data (as reported in the literature) to refine and expand the exposure, toxicity, and risk characterization components of the risk assessment process. The emphasis on chemical analyses, bioassessments, laboratory data, or modeling will depend on the availability of methods for each

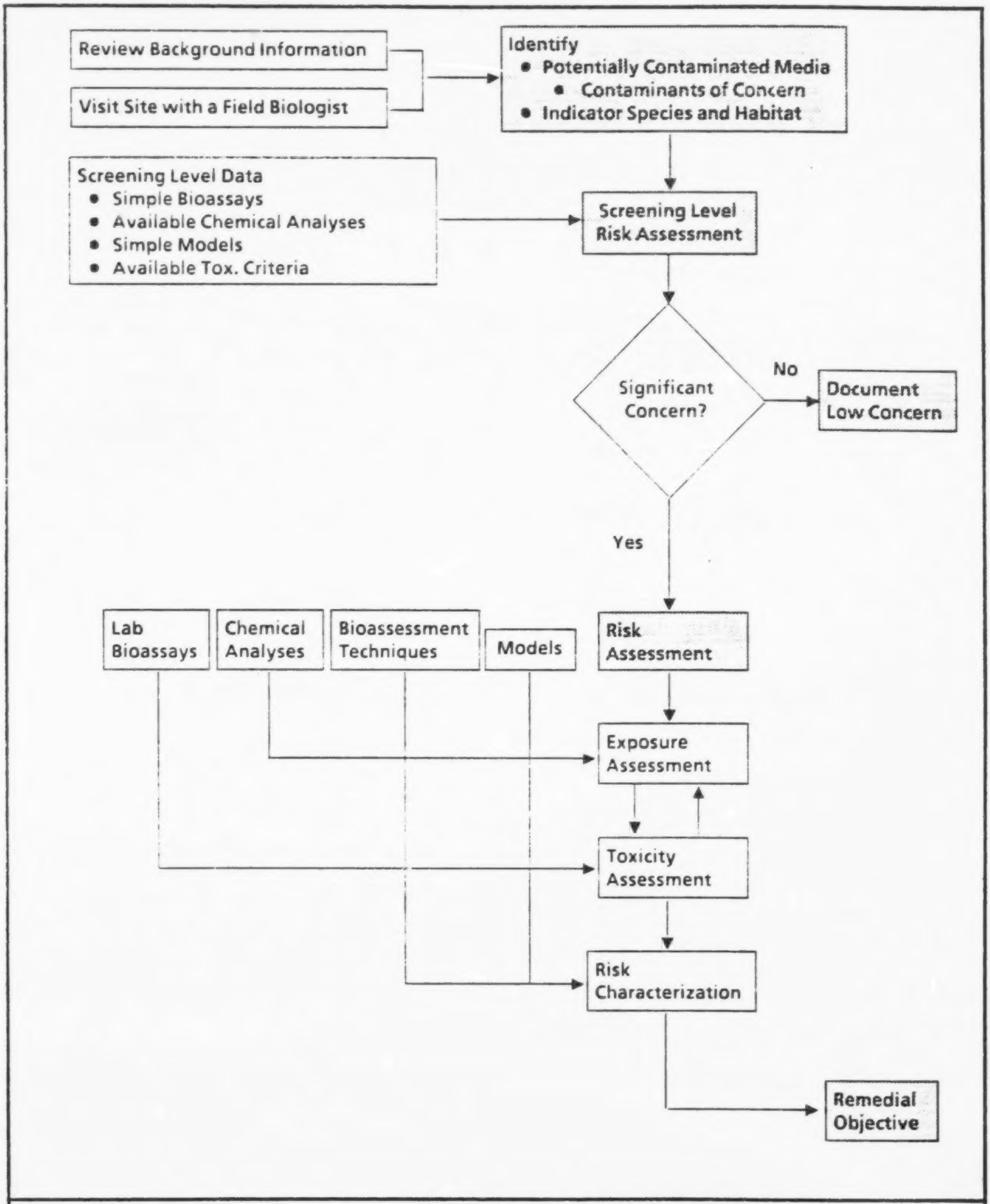

Review Background Information
Visit Site with a Field Biologist
Identify
• Potentially Contaminated Media
• Contaminants of Concern
• Indicator Species and Habitat
Screening Level Data
• Simple Bioassays
• Available Chemical Analyses
• Simple Models
• Available Tox. Criteria
Screening Level Risk Assessment
Significant Concern?
No
Document Low Concern
Yes
Lab Bioassays
Chemical Analyses
Bioassessment Techniques
Models
Risk Assessment
Exposure Assessment
Toxicity Assessment
Risk Characterization
Remedial Objective

FIGURE 3. OVERVIEW OF ECOLOGICAL RISK ASSESSMENT

TABLE 3-1

ELEMENTS OF AN ECOLOGICAL RISK ASSESSMENT FOR SUPERFUND SITES

I. DEFINITION OF OBJECTIVES

A. Assess Probability of Adverse Biological/Ecological Effects related to Site Contamination

1. Present risk
2. Future risk
3. Past risk

B. Support Feasibility Studies for Remedial Action

1. Assess risk related to remedial action alternatives
2. Develop cleanup criteria

II. SITE CHARACTERIZATION AND POTENTIAL RECEPTORS

A. Contamination

1. Extent of contamination
2. Potential sources
3. Contaminants of potential concern

B. Habitats

1. Characteristic species
2. Trustee resources and endangered species
3. Other species (e.g., economically important species)
4. Potential indicator species for each habitat of concern (including consideration of reference-area characteristics, especially in cases where local species populations may be absent due to site contamination)

C. Species Profiles

1. Abundance
2. Spatial/temporal distribution
3. Life history analysis
4. Sensitive/life stages

TABLE 3-1 (CONTINUED)

III. SELECTION OF CHEMICALS, SPECIES, AND ENDPOINTS FOR RISK ASSESSMENT

A. Selection of Contaminants

1. Criteria for selection
   a) persistence
   b) high bioaccumulation potential
   c) toxicity
   d) elevation above naturally occurring levels
2. Selected contaminants

B. Selection of Indicator Species and Possible Endpoints

1. Criteria for selection
   a) Importance to ecological system
   b) Sensitivity
   c) Relevance to human beneficial uses
   d) Availability of practical methods for prediction and measurement
   e) Trustee Species or Regulatory endpoint
2. Selected endpoints and indicator species

IV. EXPOSURE ASSESSMENT

A. Source Characterization

B. Transport and Fate Analysis

1. Mechanisms of migration
2. Spatial distribution of contamination
   a) Site data
   b) Model
3. Temporal trends
   a) Site data
   b) Model

C. Exposure Scenarios

D. Integrated Exposure Assessment (e.g., including population characteristics, potential avoidance behavior, exposure point concentrations of contaminants, duration and frequency of exposure)

E. Uncertainty Analysis

TABLE 3-1 (CONTINUED)

V. TOXICITY ASSESSMENT

A. Hazard Identification

  1. Results from Laboratory Toxicity Tests (Literature Review)
  2. Results from Field Studies
  3. Qualitative review of effects and weight of evidence for target endpoint in indicator species

B. Quantitative dose-response data and toxicological indices (e.g., LC_{50})

  1. Results from Laboratory Toxicity Tests
     a) Individual chemical
     b) Complex mixtures
  2. Site-specific Data
     a) Dilution bioassay experiments
     b) In situ toxicity tests
  3. Selection of Dose-Response Function or Toxicological Index

C. Uncertainty Analysis (e.g., issues of quantitative structure-activity relationships, interspecies extrapolation, acute to chronic extrapolation)

VI. RISK CHARACTERIZATION

A. Estimated Risks for Single Chemicals, Single Species, and Endpoints

B. Multiple Chemical Risk Predictions
  1. Hazard indices
  2. Site-specific data

C. Spatial-Temporal Distribution of Estimated Risks

D. Risks to Communities and Ecosystems

  1. Site-specific data
  2. Models

E. Uncertainty Analysis

F. Conclusions

approach and funding constraints as well as the goals of the assessment. The ways in which modeling efforts and field assessments can be used to refine and expand the different components of a risk assessment are discussed in more detail below.

3.1 EXPOSURE ASSESSMENT

The exposure assessment addresses the following questions:

- What biological resources are exposed to chemical contaminants?
- What are the significant pathways/routes of exposure?
- What is the magnitude, duration, and freqency of exposure?

Aquatic and terrestrial organisms can potentially be exposed via food, water, air, and soil or sediment. All of these media should be kept in mind when identifying potential exposure pathways. Animals having the same feeding and living habits (e.g., in the same ecological guild) will likely be exposed through similar pathways. Although many of the pathways are analogous to human exposure pathways, some are different or have potential for higher exposure. For example, many animals, such as some benthic invertebrates and burrowing rodents, normally ingest soil/sediment when feeding or grooming.

The quantification of the duration and magnitude of exposure is often based on sampling and chemical analysis of environmental media. If data on chemical concentration are not available for all media, or for all potential times and places of exposure, models can be used to predict exposure point concentrations.

The analysis of fate and transport of chemicals has been extensively developed for use in human health risk assessment, and many of the same concepts apply when evaluating where and when chemicals will reach biological resources. The discussion of specific transport models is beyond the scope of this document, but more information can be obtained by contacting the Center for Exposure Assessment Modeling (at EPA's Athens laboratory) or the Exposure Assessment Group (at EPA Headquarters). As with all models, the degree of confidence in predictions depends on the complexity of the system, the quality and quantity of input data, and the degree of model validation.

Chemical analyses of biota collected from the site can be an important complement to chemical analyses of water, sediment, and soil, particularly for substances that preferentially accumulate in biological tissue. Chemical concentrations in biota can be used to estimate exposure to the individual collected and may be extrapolated to other plants or animals in the area. Residues can also be used to estimate exposure to predators via the food web. Bioaccumulation may be an important indication of the availability of waste site contaminants to biota. For example, low concentrations of very insoluble compounds such as PCBs may not be detectable in water but may still result in substantial bioaccumulation in aquatic organisms. As a result, bioaccumulation data for PCBs may provide evidence of off-site migration that might otherwise go undetected by chemical analysis of water alone. Concentrations of chemicals in biota can also be estimated in certain situations by using transfer factors or bioconcentration factors. For example, uptake factors are available to calculate plant concentrations based on soil concentrations, correlations are available to calculate concentrations of chemicals in worms based on soil concentration, and bioconcentration factors can be used to estimate residues in fish and aquatic invertebrates.

If daily doses of contaminant intake are to be calculated, estimates of the intake of food or water are needed. The amount of each food type eaten by terrestrial and aquatic biota can be obtained in the literature for many species. Variations in food consumption throughout the year and at different life stages should be considered. For example, robins and woodcock eat mostly worms during the spring. If these worms have high chemical residues from living in contaminated soil, then the birds' short-term dose could be higher in the spring. Similarly, many aquatic organisms have vastly different feeding habits at different life stages. For example, young perch feed primarily on plankton and benthic invertebrates, whereas adult perch are more piscivorous.

The frequency of exposure is a difficult parameter to estimate for mobile organisms, since many animals have large home or feeding ranges. Avoidance behavior may also be a factor, particularly in cases of contaminated water. For terrestrial wildlife, a rough estimate of the frequency of exposure could be obtained by assuming that the animal spends equal time in each part of its range. For acute exposures, however, the dose resulting from the ingestion of one prey organism should also be calculated.

3.2 TOXICITY ASSESSMENT

The following questions are addressed during the toxicity assessment:

- What are the potential toxic effects of these chemicals?
- What are the physical, chemical, and metabolic properties of the chemicals?

o What is the relationship between the amount of exposure to each chemical of concern and the biological effect (dose-response assessment?)

The toxicity assessment is often conceptually divided into two steps; hazard identification and dose-response assessment. In the hazard identification step, the potential toxic endpoints of the chemicals or complex mixture are identified. There are currently no endpoints that are universally accepted to represent the environmental values we are mandated to protect under SARA[2]. A variety of responses have been used in laboratory and field tests to determine the biological effects of toxic substances, the most common toxic endpoint being death of the organism. Other endpoints frequently evaluated include developmental abnormalities, behavioral changes, changes in reproductive success and other physiological effects such as alteration of growth and respiration. Some of the endpoints that have been used in laboratory and field tests, and that may be useful for Superfund ecological assessments, are summarized in Table 3-2. Although the description of specific methods for measuring particular endpoints is beyond the scope of this document, more detail on the techniques and parameters used to quantify responses is given in Table 3-3.

The dose-response assessment has traditionally been based on laboratory toxicity tests using a single chemical. Laboratory data are readily available for many chemicals and species (particularly aquatic species). Models can be used to expand and refine laboratory data in a variety of ways, by quantifying dose-response curves, and by extrapolating toxicity data between species, to different time periods, or to other chemicals with similar structures.

Site-specific approaches to toxicity assessment include laboratory bioassays (using media collected from the site), in situ bioassays and field surveys. Laboratory bioassays can be used to assess the toxicity of the specific mixture of chemicals found at the site under controlled conditions. These bioassays can be used to develop site-specific dose-response curves, no effect levels or low effect levels, by using sequential dilutions of the toxic medium. In situ bioassays or surveys can further refine toxicity estimates by taking into consideration local species and site-specific factors influencing exposure.

Bioassays are particularly useful in estimating the toxicity of biologically active compounds present at waste sites that are not measured or detected in standard chemical analyses. In addition,

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[2] The subject of endpoints is discussed more thoroughly in Chapter 2 of Ecological Assessments of Hazardous Waste Sites (USEPA, 1989).

TABLE 3-2

POSSIBLE ENDPOINTS FOR USE IN ECOLOGICAL RISK ASSESSMENTS

Organism level

1. Mortality*
2. Sublethal effects*
    - a) Changes in growth
    - b) Changes in behavior
    - c) Changes in endurance
    - d) Changes in susceptibility (e.g., to disease, parasites, or predation)
    - e) Histopathological abnormalities (e.g., cancer, liver necrosis)*
    - f) Gross abnormalities*
    - g) Changes in bone development
    - h) Blood chemistry and hematology
    - i) Mutagenicity
    - j) Biochemical changes (e.g., enzyme or protein activity)**
    - k) Reproductive impairment*

Population level

1. Species abundance*
2. Reproductive potential*
3. Distribution (including local extinction)*

TABLE 3-2 (CONTINUED)

Community level

1. Species composition, richness, diversity, evenness*
2. Extinction (local)*
3. Biomass
4. Interspecies relationships

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* Most useful for ecological risk assessment

** Particularly used in terrestrial systems

TABLE 3-3

TECHNIQUES AND PARAMETERS USED TO QUANTIFY TOXIC RESPONSES

END POINT	TECHNIQUE	PARAMETERS OF MEASURE	COMMENTS
A. **ORGANISM LEVEL**			
1 Mortality	Toxicity test, observation	LD, LC, NOEL, literature comparisons, presence of moribund individuals	Used for both terrestrial and aquatic organisms; primarily an endpoint in laboratory studies
2. Growth	Toxicity test, observation	NOEL, size at a standard age, comparison to control sites(s) and literature	Used for both terrestrial and aquatic organisms, primarily an endpoint in laboratory studies
3 Behavior	Observation, controlled tests	Avoidance, feeding, ambulation, social interactions, "learning" abililty	Used primarily for aquatic organisms in laboratory studies
4. "Cough" response	Observation	Aquatic (fish) reaction to irritant	Used primarily for aquatic organisms in laboratory studies
5 Endurance	Observation, controlled tests	Speed of movement, oxygen consumption, time to fatigue (primarily aquatic)	Used for aquatic organisms in laboratory studies
6 Increased susceptibility, disease, parasites, predation	Diagnosis, assumptions (predation)	Comparison to control organisms, literature	Used for both terrestrial and aquatic organisms, primarily an endpoint in laboratory studies
7. Gross and histopathological abnormalities	Observation, histopathology	Comparison to control site(s) literature or standard	Used for both terrestrial and aquatic organisms, used in both laboratory and field studies
8 Bone Development	Mechanical stress tests	Primarily for fish for toxaphene, PCBs, kepone, lead, cadmium (and other) comparison of values to controls and literature	Used primarily for aquatic organisms (some terrestrial) in laboratory studies

TABLE 3-3 (Continued)

TECHNIQUES AND PARAMETERS USED TO QUANTIFY TOXIC RESPONSES

END POINT	TECHNIQUE	PARAMETERS OF MEASURE	COMMENTS
A. Organism Level (Continued)			
9 Blood chemistry	Chemical analyses and diagnosis	Non specific stress indicator, comparison to controls, literature and standards	Used for both terrestrial and aquatic organisms; primarily an endpoint in laboratory studies
10. Mutagenicity	DNA synthesis, bacterial revertancy, cell mutation	Comparison to standards, controls, literature; good for single compound tests	Used for both terrestrial and aquatic organisms; primarily an endpoint in laboratory studies
11 Biochemical			
a Enzyme activity	Enzyme assay (chemical)	Inhibitionof enzyme (e g , cholinesterase for organophosphates and carbonates. ALAD for lead, etc	Used for both terrestrial and aquatic organisms; primarily an endpoint in laboratory studies
	Enzyme assay	Levels of mixed function oxidases for aromatic and halobiphenyls	Used for both terrestrial and aquatic organisms; primarily an endpoint in laboratory studies
b Protein activity	Metallothionein assay	Metallothionein level reflects bioavailability of metals; comparison to controls and literature	Used for both terrestrial and aquatic organisms; primarily an endpoint in laboratory studies
	Glutathione assay	Glutathione level depletion or induction reflect activity of certain hydrocarbons, subjective comparison to literature	Used for both terrestrial and aquatic organisms; primarily an endpoint in laboratory studies
c Reproductive impairment	Diagnosis, observation, controlled doseage tests	Teratogenesis, hormonal assays, behavior, hatching/birthing success, nest/young abandonment, reproductive development	Used for both terrestrial and aquatic organisms; used in both laboratory and field settings

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TABLE 3-3 (Continued)

TECHNIQUES AND PARAMETERS USED TO QUANTIFY TOXIC RESPONSES

END POINT	TECHNIQUE	PARAMETERS OF MEASURE	COMMENTS
B. Population Level (species)			
1 Abundance/density	Capture-recapture, removal plot mapping, transects, home range determinations, etc.	Comparison of population estimates to control or values in the literature (HEP, others)	Used for both terrestrial and aquatic organisms; primarily an endpoint in field studies
2. **Reproductive Impairment**	Analysis of population sex and age structure age-specific facundity	Comparison to control and literature	Used for both terrestrial and aquatic organisms; primarily an endpoint in field studies
3. Distribution	Observation, surveys	Comparison of distribution to control or literature (local range maps), habitability assessment	Used for both terrestrial and aquatic organisms; primarily an endpoint in field studies
C. Community Level			
1 Biomass assessment	Primary and secondary productivity, standing crop measurements	Comparison to control sites and literature	Used for both terrestrial and aquatic organisms; used in both laboratory and field settings
2 **Species diversity/richness**	Population assessment techniques	Comparison to control sites and literature	Used for both terrestrial and aquatic organisms; used in both laboratory and field settings
3. **Interspecies relationships (dominant vs. diminished)**	Population assessment techniques	Comparison to control sites and literature	Used for both terrestrial and aquatic organisms; used in both laboratory and field settings
4. Niche-guild analysis	Population assessment techniques	Subjective-comparison to control sites and literature (trying to determine if available niches are occupied/filled)	Used for both terrestrial and aquatic organisms; used in both laboratory and field settings.
5 **Indicator species**	Surveys, observations	Presence or absence (sensitive species); comparison to control sites and literature	Used for both terrestrial and aquatic organisms; used in both laboratory and field settings.

when water or sediment quality criteria or toxicological data are unavailable for chemical contaminants, bioassays make it possible to evaluate the toxic responses associated with these contaminants. Furthermore, because there are no means at present to accurately predict interactive effects of complex mixtures of chemicals, the measurement of a biological response to the suspected contaminated material can provide a direct estimate of toxicity. EPA has developed several bioassay methods manuals for assessing acute (EPA 1985a, EPA 1987) and chronic (EPA 1985b, EPA 1988) toxicity.

Several site- or region-specific approaches have been developed to assess the toxicity of contaminated sediments using a combination of bioassays and chemical analyses. Three of these are the Apparent Effects Threshold (AET) (PTI Environmental Services 1987), Screening Level Concentrations (SLC) (Battelle 1986), and the Sediment Quality Triad (SQT) approaches (Long and Chapman 1985). An AET is the chemical concentration above which statistically significant effects are observed in a data set with paired biological and chemical observations. The SLC estimates the sediment concentrations of a contaminant above which less than 95 percent of the total enumerated species of benthic infauna are present. The SQT approach uses a combination of sediment chemistry, sediment bioassays, and in situ biological effects data (e.g., benthic infaunal abundance, bottomfish histopathology) to derive "minimal" to "severe" biological effects criteria. These site-specific criteria can then be used with chemical concentration data to estimate the extent of adverse effects. However, the application of the criteria to other sites with different ecological communities is associated with a great deal of uncertainty.

3.3 RISK CHARACTERIZATION

In the risk characterization part of the assessment, the results of the toxicity and exposure assessments are combined to address the following questions:

- o What is the probability that adverse effects to the receptors of concern will result from the estimated exposure?
- o What is the degree of confidence in the risk estimate?

Risk estimates and associated confidence statements may be expressed qualitatively or quantitatively depending on the purpose of the assessment and the availability of data and appropriate models. The simplest and most common quantitative approach is the quotient method in which an index expected to be roughly correlated with risk is derived (e.g., the observed chemical concentration divided by the LC50 for the indicator species and endpoint). This approach is routinely used by the EPA Hazard Evaluation Division in the Office of Pesticide Programs (Urban and Cook 1986). An estimate of the probability of exceeding a criterion can be derived given quantitative estimates of variance associated with the mean concentration of a chemical, the criterion of interest, or both.

Some bioassessment techniques can be very useful in characterizing current risk at a site: measurements of adverse effects to sample populations or communities can be used to estimate risk to the entire population or community. The fourth column of Table 3-3 indicates which endpoints can be used to document effects in the field. One form of direct response that may be measurable is the increase in specific physiological disorders that can be induced by exposure to toxic substances. These disorders include such effects as fin erosion, lesions or cancers of specific organs, reduced growth, changes in reproductive success, and changes in the activity level of one or more enzyme systems in response to contaminant exposures.

While assessments of physiological disorders and disease evaluate the health or condition of individual organisms in the impacted environment, assessment of community impacts is based on the measurements of the numbers and identities of the organisms present. Adverse responses to toxic substances in natural communities may result in reduced viability in the affected populations or the community. Changes in the total numbers or biomass of organisms present, the kinds of species present, the size and ages of the members of the populations and the relative numbers of different species are some of the community attributes that can be altered by chemicals. Direct comparisons of these attributes for a population in the contaminated area with populations from reference areas of comparable habitat or with baseline data can be used to detect toxic effects.

Some bioassessment approaches, particularly those that are used to directly assess impacts on populations and communities, have some important limitations. Natural populations normally have very high spatial and temporal variability and suitable uncontaminated reference areas may be difficult to locate. The environmental variability often makes it difficult to distinguish a minor change that is the result of exposure to toxic substances from one that is the result of other processes. Although the procedures for field bioassessments are generally well-developed, these assessments tend to be expensive and time-consuming. Another limitation of these approaches is the difficulty in determining the actual extent of exposure to specific contaminants, particularly for fish and other mobile organisms. In cases where adverse effects are not linked to exposure to specific chemicals, it may be difficult to develop clean-up criteria, or associate the adverse effects with a particular source. The primary advantage of these techniques is that they directly demonstrate that harmful impacts have occurred at the site. In addition, the results are relatively easy to relate to environmental impacts for people with limited technical background.

A few sophisticated models are available for certain situations (e.g., lakes and ponds) that enable predictions to be made regarding endpoints at the community level given exposure and toxicity data at the species level. Often, however, it is not possible to apply these models or to conduct a field survey investigating the occurrence of effects at the population or community level. In these cases, several factors can be qualitatively considered to assess the possibility of long-term impacts on natural populations and communities. These include:

- The persistence of the chemical.
- The areal extent of contamination.
- The presence of a potential replacement population.
- The adverse effects expected.
- The life cycle characteristics of the animal (in particular, death rate, birth rate).
- The presence of other stressors in the environment.

4.0 ECOLOGICAL RISK ASSESSMENT FLOW DIAGRAMS

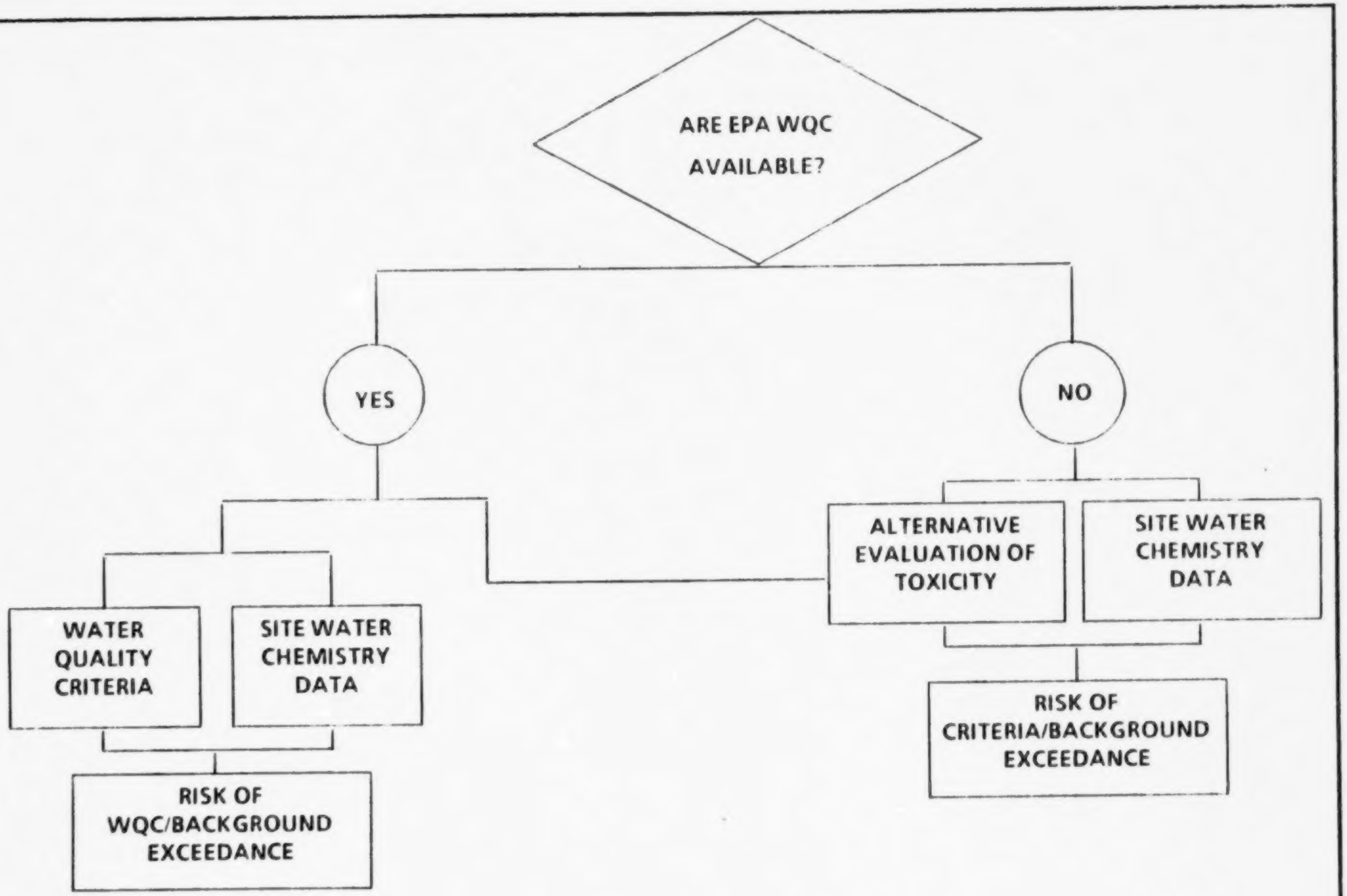
Specific approaches that have been shown to be useful in assessing risk at both the screening and more detailed levels are illustrated in Figures 4, 5, 6, and 7. In general, these procedures yield estimates of risk for individual organisms. Hence, if the objective of the assessment is to evaluate the probability of impacts at the population or community level, additional extrapolation (usually done qualitatively at this time) will be necessary.

The procedures shown in Figures 4 and 5 are primarily used for aquatic systems. A screening assessment used for chemicals in water (shown in Figure 4) may be a simple comparison of chemical concentrations in water to available EPA Ambient Water Quality Criteria, whenever these criteria are available. Evaluation of site contamination relative to water quality criteria is usually supported by a qualitative assessment of contaminant toxicity based on available literature. If EPA Ambient Water Quality Criteria are not available, an alternative evaluation of toxicity may be conducted using laboratory or field data from the literature. Such evaluations are often based on comparisons of contaminant concentrations at the site with No-Observed Adverse Effect Levels (NOAEL) derived from laboratory experiments. In any case, the applicability of available chemical-specific criteria or NOAELs to complex mixtures of contaminants at the site should be evaluated.

Analogous approaches using chemical analyses of sediments are shown in Figure 5. On the left-hand side of the diagram, chemistry and effects data collected concurrently in the field are used to derive regional sediment criteria. On the right-hand side of the diagram, an equilibrium partitioning model is used to derive the sediment concentration that corresponds to a water quality criterion. The use of one method or the other will depend on the number of chemicals present in the sediment, the resources available, and the objectives of the assessment. It should be noted, however, that these two approaches may not yield the same chemical criteria for a given site.

The approaches shown in Figure 6 were developed for aquatic systems, but can be easily adapted for terrestrial systems. In particular, tissue residues that correspond to toxic effects are available in the literature for some chemicals and can be used to develop criteria. These criteria can then be compared to tissue residues collected at a site, provided, of course, that the tissue collected was the same tissue used to derive the criterion.

Figure 7 illustrates an approach that can be applied to terrestrial systems. Chemical concentrations in water, soil, air, and food items are measured or estimated using models. These concentrations are used along with assumptions regarding intake in much the same way as is currently done in human health risk assessments. Although there is no readily available compilation of intake assumptions for wildlife, these values are often available in the literature.


ARE EPA WQC AVAILABLE?
YES
NO
WATER QUALITY CRITERIA
SITE WATER CHEMISTRY DATA
RISK OF WQC/BACKGROUND EXCEEDANCE
ALTERNATIVE EVALUATION OF TOXICITY
SITE WATER CHEMISTRY DATA
RISK OF CRITERIA/BACKGROUND EXCEEDANCE

WQC - WATER QUALITY CRITERIA

FIGURE 4. ASSESSMENTS BASED ON CHEMICAL CONCENTRATIONS IN WATER

Reproduced from best available copy.

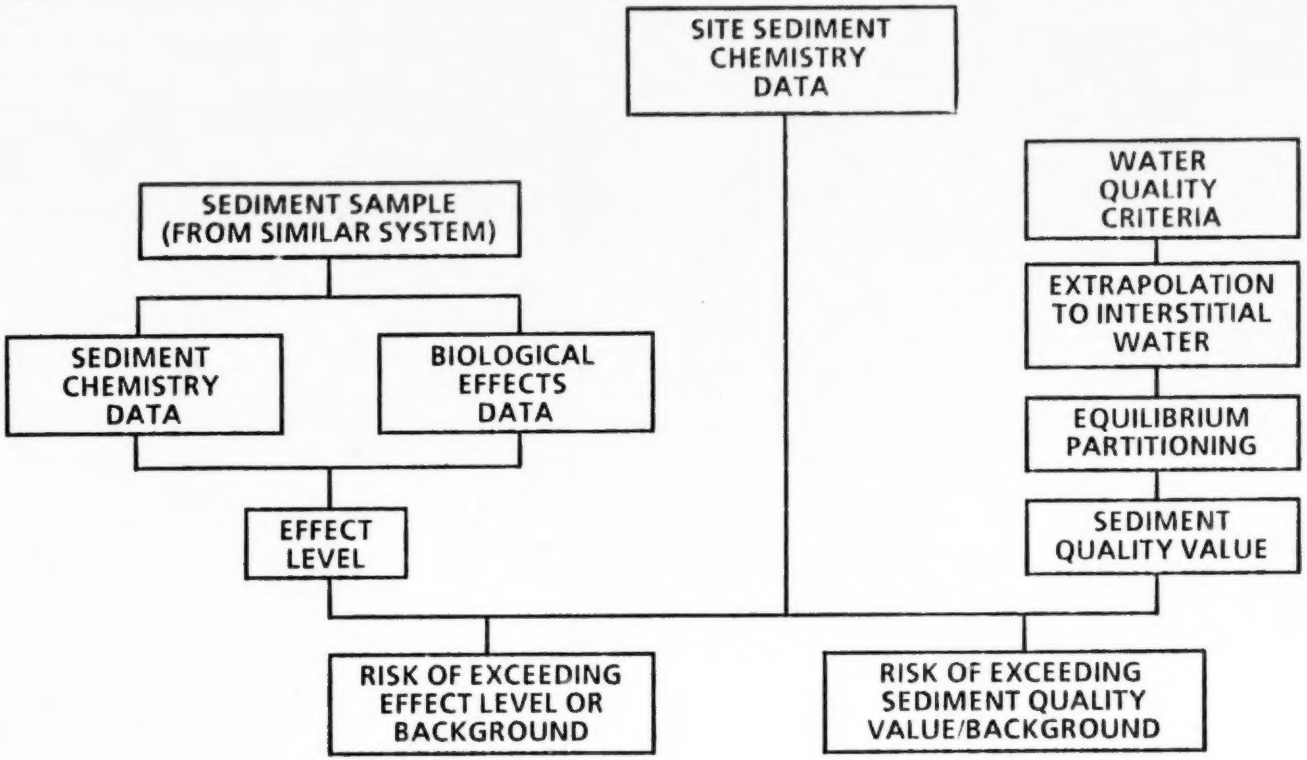
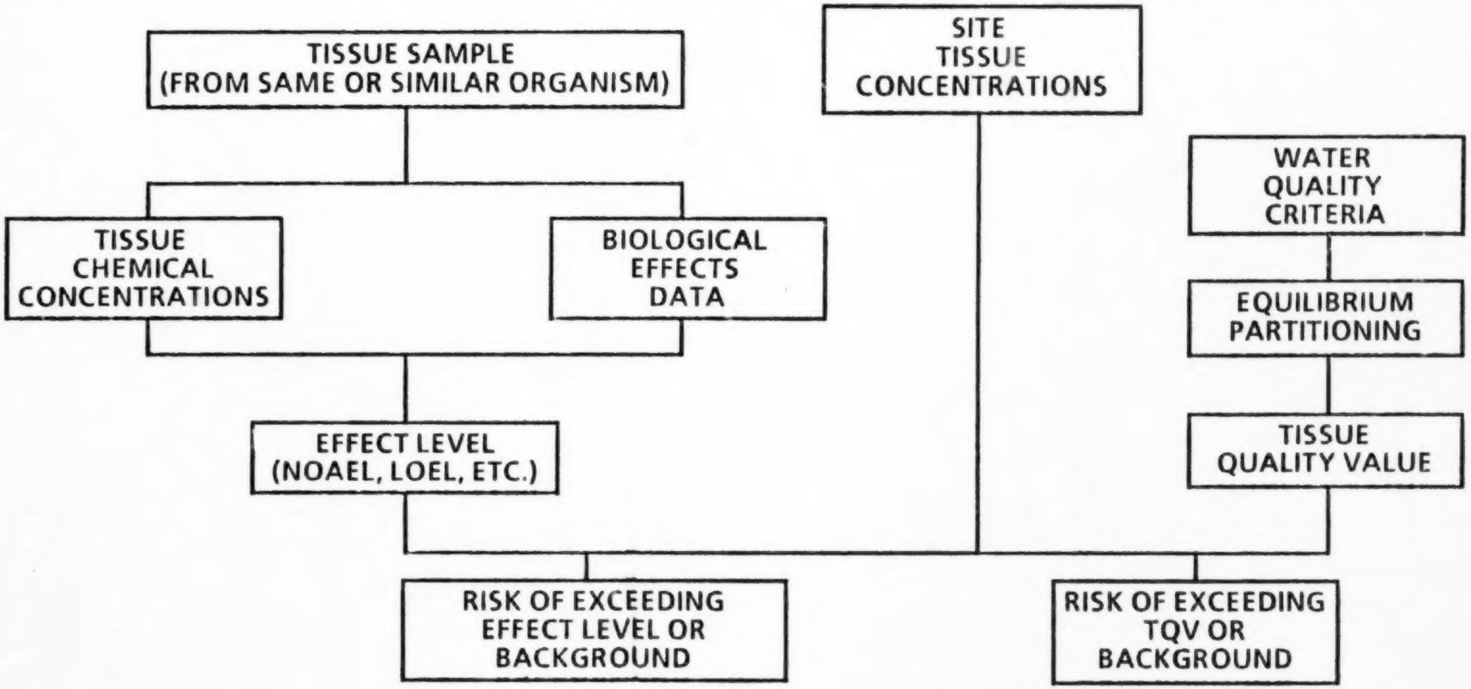

SITE SEDIMENT CHEMISTRY DATA
SEDIMENT SAMPLE (FROM SIMILAR SYSTEM)
SEDIMENT CHEMISTRY DATA
BIOLOGICAL EFFECTS DATA
EFFECT LEVEL
WATER QUALITY CRITERIA
EXTRAPOLATION TO INTERSTITIAL WATER
EQUILIBRIUM PARTITIONING
SEDIMENT QUALITY VALUE
RISK OF EXCEEDING EFFECT LEVEL OR BACKGROUND
RISK OF EXCEEDING SEDIMENT QUALITY VALUE/BACKGROUND

FIGURE 5. ASSESSMENTS BASED ON CHEMICAL CONCENTRATIONS IN SEDIMENTS


TISSUE SAMPLE (FROM SAME OR SIMILAR ORGANISM)
SITE TISSUE CONCENTRATIONS
WATER QUALITY CRITERIA
TISSUE CHEMICAL CONCENTRATIONS
BIOLOGICAL EFFECTS DATA
EQUILIBRIUM PARTITIONING
EFFECT LEVEL (NOAEL, LOEL, ETC.)
TISSUE QUALITY VALUE
RISK OF EXCEEDING EFFECT LEVEL OR BACKGROUND
RISK OF EXCEEDING TQV OR BACKGROUND

NOAEL - NO OBSERVED ADVERSE EFFECTS LEVEL
LOEL - LOWEST OBSERVED EFFECT LEVEL
TQV - TISSUE QUALITY VALUES

FIGURE 6. ASSESSMENTS BASED ON CHEMICAL CONCENTRATION IN TISSUES

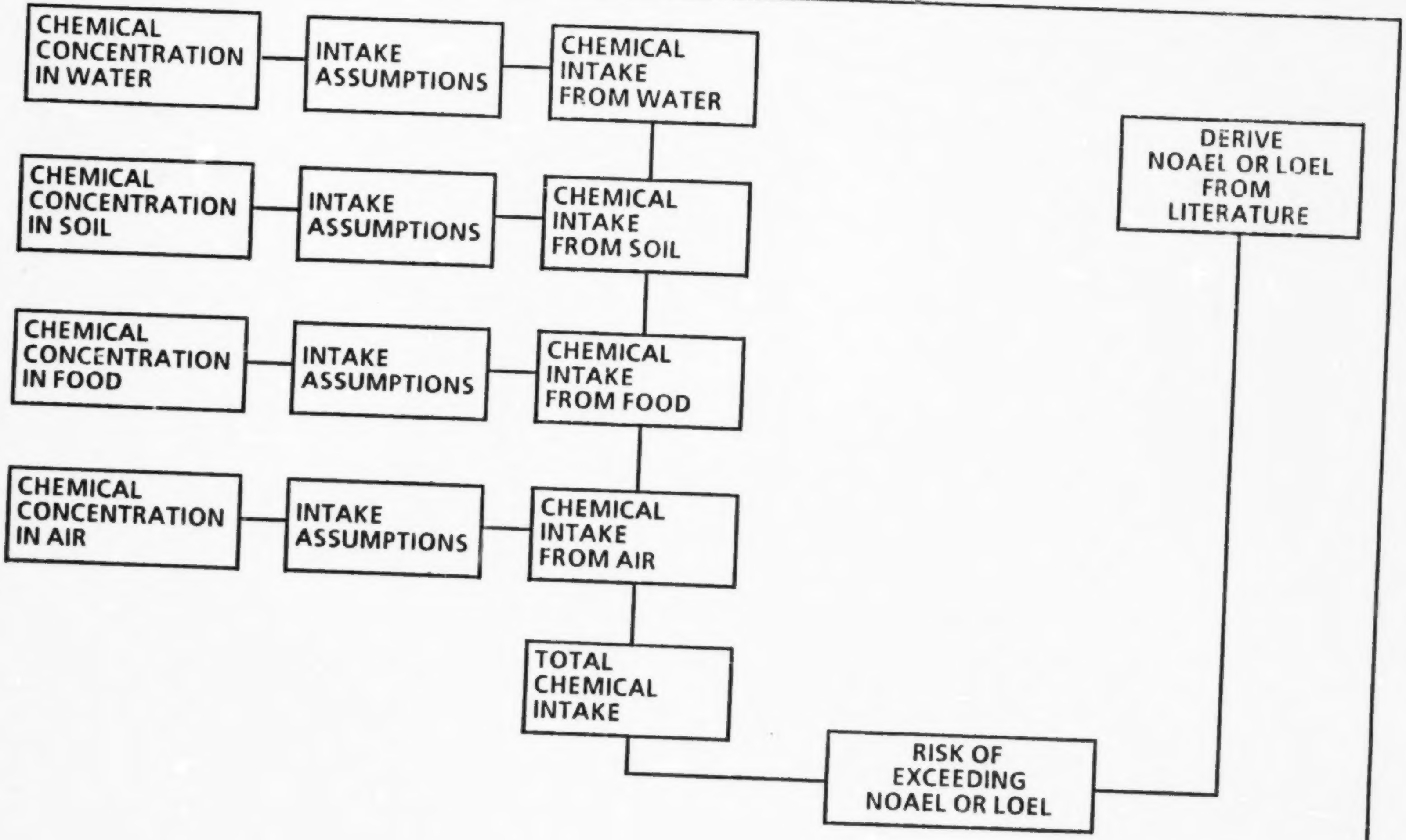

CHEMICAL CONCENTRATION IN WATER
INTAKE ASSUMPTIONS
CHEMICAL INTAKE FROM WATER
CHEMICAL CONCENTRATION IN SOIL
INTAKE ASSUMPTIONS
CHEMICAL INTAKE FROM SOIL
CHEMICAL CONCENTRATION IN FOOD
INTAKE ASSUMPTIONS
CHEMICAL INTAKE FROM FOOD
CHEMICAL CONCENTRATION IN AIR
INTAKE ASSUMPTIONS
CHEMICAL INTAKE FROM AIR
TOTAL CHEMICAL INTAKE
RISK OF EXCEEDING NOAEL OR LOEL
DERIVE NOAEL OR LOEL FROM LITERATURE

FIGURE 7. ASSESSMENTS BASED ON CHEMICAL INTAKE

5.0 REFERENCES

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APPENDIX 1

USEFUL WATER, SEDIMENT, SOIL, AND BIOLOGICAL PARAMETERS FOR ECOLOGICAL RISK ASSESSMENT

1.0 Water Quality Parameters

1.1 Hardness - may influence the toxicity of many chemicals, and is needed to calculate ambient water quality criteria for most metals.

1.2 pH - affects chemicals toxicity and the presence of receptor organisms.

1.3 Dissolved oxygen (D.O.) - low D.O. may indicate chemical contamination and makes habitat unsuitable for aerobic organisms.

1.4 Salinity - to determine type of habitat and its suitability for receptor organisms (marine, estuarine, freshwater).

1.5 Temperature - may influence toxicity and bioavailability of contaminants, and presence of receptor organisms.

1.6 Conductivity - indicates chemical contamination.

1.7 Total suspended solids - hydrophobic chemicals (PCBs, PAHs etc.) sorb to silts and clays, therefore they may be removed from the water column and accumulated in the sediments.

2.0 Hydraulic Characteristics

All of the following hydraulic characteristics are needed in order to calculate flushing rates or hydraulic retention times, which are important factors for modeling fate and transport of chemicals. The parameters needed, however, will vary from site to site.

2.1 Rivers and Streams

2.1.1 Flow Rate - average flow, maximum, minimum, seasonal variations

2.1.2 Depth - average depth, seasonal variations

2.1.3 Groundwater recharge and discharge

APPENDIX 1 (Cont.)

2.2 Estuaries and Embayments

- 2.2.1 Speed and direction of currents - diurnal variations, seasonal variations, climatic variations
- 2.2.2 Tidal cycle, tidal heights
- 2.2.3 Extent of Saltwater incursion
- 2.2.4 Depth - average depth, tidal variations
- 2.2.5 Area
- 2.2.6 Groundwater recharge and discharge

2.3 Lakes

- 2.3.1 Area
- 2.3.2 Volume
- 2.3.3 Depth
- 2.3.4 Depth to thermocline
- 2.3.5 Surface water inputs and outflows
- 2.3.6 Groundwater recharge and discharge

3.0 Physical Sediment Parameters

3.1 Particle size distribution - geographic distribution of sediment size is used for determining possible benthic organisms present and for determining depositional areas of suspended particulates.

3.2 Fraction organic carbon or total organic carbon - hydrophobic toxic organic chemicals sorb to the organic component of sediments. This parameter is essential to the application of sediment quality criteria for organic chemicals, and for using predictive models of toxicity and bioaccumulation.

3.3 Physical description - color, odors (e.g., hydrogen sulfide - rotten egg), and general type (carbonate, silicate).

3.4 pH - is needed to apply some Water Quality Criteria, and can be used to interpret the absence of biota in an area.

3.5 Benthic Oxygen conditions (e.g., anaerobic, disaerobic, aerobic) - are needed to predict the form or valence state of the chemical in sediments, which may influence toxicity or fate and transport.

3.6 Water Content - is needed for some fate and transport models and to convert dry - weight sediment concentrations to wet weight.

4.0 Physical Soil Characteristics

The first four parameters are often needed as input to fate and transport models.

4.1 Particle size

4.2 Permeability/Porosity

4.3 Fraction organic carbon/total organic carbon

4.4 Water content

4.5 pH - controls solubility and mobility of heavy metals

4.6 eH - redox potential influences solubility and mobility of heavy metals

4.7 Physical description - color, odor, type of soil, etc.

5.0 Biological data

5.1 Dry Weight Chemical Concentration - Contaminant concentration per dry weight of tissue (preferred over wet weight concentrations).

5.2 Whole Body or Specific Organ Chemical Concentration - used for food chain accumulation or chronic toxic effects.

5.3 Edible Portion Chemical Concentration - used for comparing to FDA limit or for looking at human health implications.

APPENDIX 1 (cont.)

5.4 Percent Moisture - To convert dry weight chemical concentrations to wet weight chemical concentrations

5.5 Lipid content - Important in the evaluation of body burden data for organic lipophilic pollutants.

5.6 Size/Age - Bioaccumulation of contaminants is often size or age dependent.

5.7 Life History Stage - Younger life stages are more susceptible to toxic effects from contaminants.

5.8 Feeding Group - Mode of feeding will influence bioaccumulation potential and possible food chain effects.

TO THE READER:

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